



MELPHALAN HYDROCHLORIDE FOR INJECTION

SAFETY DATA SHEET

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY

Product Identifier

Product name: Melphalan Hydrochloride for Injection

Intended Use Of The Product

Use of the substance/preparation: Pharmaceutical. Cancer chemotherapy agent. Powdered form of Melphalan is supplied with a sterile diluent intended to be added prior to administration. Use only as directed. Refer to product insert for usage instructions and product information.

Name, Address, And Telephone Of The Responsible Party

Supplier:

Mylan Institutional LLC
1718 Northrock Court
Rockford, IL 61003 USA
800.848.0462

www.mylan.com

Manufacturer:

Mylan Teoranta
Galway, Ireland

Emergency Telephone Number

Emergency number : +1 877-446-3679

2. HAZARDS IDENTIFICATION

Patients/Consumers: Please refer to the product information insert or product label for appropriate consumer-specific information about this product when used according to the physician's directions. Pharmaceutical Agent – Handling of this product in its final form presents minimal occupational exposure risk.

MELPHALAN HYDROCHLORIDE (lyophilized powder)

Classification of the Substance or Mixture

Classification (GHS-US)

Acute Tox. 1 (Oral)	H300
Acute Tox. 1 (Dermal)	H310
Acute Tox. 2 (Inhalation:dust,mist)	H330
Muta. 1B	H340
Carc. 1A	H350
Repr. 2	H361

Label Elements

GHS-US labeling

Hazard pictograms (GHS-US) :



Signal word (GHS-US) :

Danger

Hazard statements (GHS-US) :

H300+H310+H330 - Fatal if swallowed, in contact with skin or if inhaled
H340 - May cause genetic defects
H350 - May cause cancer
H361 - Suspected of damaging fertility or the unborn child

Precautionary statements (GHS-US) :

P201 - Obtain special instructions before use.
P202 - Do not handle until all safety precautions have been read and understood.
P260 - Do not breathe dust.
P262 - Do not get in eyes, on skin, or on clothing.
P264 - Wash hands, forearms, and exposed areas thoroughly after handling.

P270 - Do not eat, drink or smoke when using this product.
 P271 - Use only outdoors or in a well-ventilated area.
 P280 - Wear protective gloves/protective clothing/eye protection/face protection.
 P284 - Wear respiratory protection.
 P301+P310+P330 - IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician. If swallowed, rinse mouth.
 P304+P340 - IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
 P308+P313 - If exposed or concerned: Get medical advice/attention.
 P310 - Immediately call a POISON CENTER or doctor/physician.
 P361 - Remove/Take off immediately all contaminated clothing.
 P363 - Wash contaminated clothing before reuse.
 P405 - Store locked up.
 P501 - Dispose of contents/container according to local, regional, national, provincial, territorial, and international regulations.

Other Hazards Not available

Unknown acute toxicity (GHS US) Not available

STERILE DILUENT

Classification Of The Substance Or Mixture

Classification (GHS-US)

Flam. Liq. 2 H225
 Skin Irrit. 2 H315
 Eye Irrit. 2B H320

Label Elements

GHS-US labeling

Hazard pictograms (GHS-US)



Signal word (GHS-US)

: Danger

Hazard statements (GHS-US)

: H225 - Highly flammable liquid and vapor
 H315 - Causes skin irritation
 H320 - Causes eye irritation

Precautionary statements (GHS-US)

: P210 - Keep away from heat/sparks/open flames/hot surfaces. - No smoking.
 P233 - Keep container tightly closed.
 P240 - Ground/bond container and receiving equipment.
 P241 - Use explosion-proof electrical/ventilating/lighting equipment.
 P242 - Use only non-sparking tools.
 P243 - Take precautionary measures against static discharge.
 P264 - Wash hands, forearms, and exposed areas thoroughly after handling.
 P280 - Wear protective gloves/protective clothing/eye protection/face protection.
 P303+P361+P353 - IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.
 P305+P351+P338 - If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
 P332+P313 - If skin irritation occurs: get medical advice/attention.
 P337+P313 - If eye irritation persists: get medical advice/attention.
 P362 - Take off contaminated clothing.
 P370+P378 - In case of fire: Use appropriate media for extinction.
 P403+P235 - Store in a well-ventilated place. Keep cool.
 P501 - Dispose of contents/container according to local, regional, national, territorial, provincial, and international regulations.

Other Hazards Not available

Unknown acute toxicity (GHS US) Not available

3. COMPOSITION/INFORMATION ON INGREDIENTS

MELPHALAN HYDROCHLORIDE (lyophilized powder)

Mixture

Name	Product identifier	% (w/w)	Classification (GHS-US)
Melphalan hydrochloride	(CAS No.) 3223-07-2	71.4	Acute Tox. 1 (Oral), H300

			Acute Tox. 1 (Dermal), H310 Acute Tox. 2 (Inhalation:dust,mist), H330 Muta. 1B, H340 Carc. 1A, H350 Repr. 2, H361
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Full text of H-phrases: see section 16

STERILE DILUENT

Mixture

Name	Product identifier	% (w/w)	Classification (GHS-US)
1,2-Propylene glycol	(CAS No.) 57-55-6	61	Flam. Liq. 3, H226 Skin Irrit. 2, H315 Eye Irrit. 2B, H320
Ethyl alcohol	(CAS No.) 64-17-5	4	Flam. Liq. 2, H225 Skin Irrit. 2, H315 Eye Irrit. 2A, H319

Full text of H-phrases: see section 16

4. FIRST AID MEASURES

Description Of First Aid Measures- Sterile Diluent and Melphalan Hydrochloride (lyophilized powder).

General: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show label if possible).

Inhalation: The risk of inhalation exposure is negligible when product is in its final packaged form. If exposed and become symptomatic, move to fresh air and get medical attention if symptoms persist.

Skin Contact: Basic hygiene and appropriate precautions should prevent skin contact. If skin contact occurs, wash affected area with soap and water for at least 15 minutes. Should skin irritation, allergic reaction, or rash occur, remove contaminated clothing (if required) and seek medical advice.

Eye Contact: The risk of eye exposure is negligible when product is in its final packaged form. If eye contact occurs, flush immediately with water for at least 15 minutes. If easy to do, remove contact lenses. Get medical attention.

Ingestion: Ingestion is not an anticipated route of exposure. If accidental ingestion occurs, flush mouth out with water and get medical attention.

MELPHALAN HYDROCHLORIDE (lyophilized powder)

Most Important Symptoms And Effects Both Acute and Delayed

General: The most common side effects include nausea, vomiting, diarrhea, temporary hair loss, skin rash. More severe side effects include fever, chills, body aches, bruising, dark colored urine, pale or yellowed skin.

Inhalation: Fatal if inhaled.

Skin Contact: Fatal in contact with skin.

Eye Contact: Direct contact with the eyes is likely irritating.

Ingestion: Fatal if swallowed.

Chronic symptoms: May cause cancer. May cause heritable genetic damage. May damage fertility or the unborn child.

Indication Of Any Immediate Medical Attention And Special Treatment Needed

If exposed or concerned, get medical advice and attention.

STERILE DILUENT

Most Important Symptoms And Effects Both Acute and Delayed

General: Irritation to eyes, skin and respiratory tract.

Inhalation: May be irritating to the respiratory tract.

Skin Contact: Causes mild skin irritation.

Eye Contact: Causes eye irritation.

Ingestion: May cause headache, nausea, dizziness, drowsiness, and loss of coordination.

Chronic symptoms: Chronic exposure may cause liver and kidney damage.

Indication Of Any Immediate Medical Attention And Special Treatment Needed

If exposed or concerned, get medical advice and attention. In the event of accidental injection, go immediately to the nearest emergency room.

5. FIREFIGHTING MEASURES

MELPHALAN HYDROCHLORIDE (lyophilized powder)

Extinguishing Media

Suitable extinguishing media: Not flammable. Use extinguishing media appropriate for surrounding fire.

Unsuitable extinguishing media: None known.

Special Hazards Arising From The Substance Or Mixture

Fire hazard: Not flammable

Explosion hazard: Product is not explosive

Reactivity: Hazardous reactions will not occur under normal conditions.

Advice For Firefighters

Firefighting Instructions: Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Do not allow run-off from fire fighting to enter drains or water courses.

Protection during firefighting: Do not enter fire area without proper protective equipment, including respiratory protection.

Hazardous Combustion Products: Carbon oxides (CO, CO₂). Nitrogen oxides. Hydrogen chloride. Hydrogen cyanide.

Other information: Refer to Section 9 for flammability properties.

STERILE DILUENT

Extinguishing Media

Suitable extinguishing media: Dry chemical powder, alcohol-resistant foam, carbon dioxide (CO₂).

Unsuitable extinguishing media: Do not use a heavy water stream. Use of a heavy stream of water may spread fire.

Special Hazards Arising From The Substance Or Mixture

Fire hazard: Highly flammable liquid and vapor.

Explosion hazard: Heat may build pressure, rupturing closed containers and spreading fire.

Reactivity: Hazardous reactions will not occur under normal conditions.

Advice For Firefighters

Firefighting Instructions: Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Do not allow run-off from fire fighting to enter drains or water courses.

Protection during firefighting: Do not enter fire area without proper protective equipment, including respiratory protection.

Hazardous Combustion Products: Carbon oxides (CO, CO₂).

Other information: Refer to Section 9 for flammability properties.

6. ACCIDENTAL RELEASE MEASURES

Unless otherwise specified, this section applies to both Sterile Diluent and Melphalan Hydrochloride (lyophilized powder).

Personal Precautions, Protective Equipment And Emergency Procedures

General measures: MELPHALAN HYDROCHLORIDE: Do not breathe dust. Do not get in eyes, on skin, or on clothing.

STERILE DILUENT: Avoid all eye and skin contact and do not breathe vapor or mist. Keep away from heat/sparks/open flames/hot surfaces – No smoking.

For Non-Emergency Personnel

Protective equipment: Use appropriate personal protection equipment (PPE).

Emergency procedures: Evacuate unnecessary personnel. Eliminate ignition sources.

For Emergency Personnel

Protective equipment: Use appropriate personal protection equipment (PPE).

Emergency procedures: If possible, stop flow of product. Ventilate area.

Environmental Precautions

Prevent entry to sewers and public waters.

Methods And Material For Containment And Cleaning Up

Methods for cleaning up: For small quantities associated with normal therapeutic use, collect spillage and transfer to a closed waste container for disposal. For large or bulk quantities, after absorption with inert material, collect spillage by sweeping up spilled material and place in a labeled, sealed container for proper disposal.

Reference To Other Sections

See heading 8, Exposure Controls and Personal Protection.

7. HANDLING AND STORAGE

Unless otherwise specified, this section applies to both Sterile Diluent and Melphalan Hydrochloride (lyophilized powder).

Precautions For Safe Handling

Patients/Consumers: Patients should adhere to the instructions provided within the product information insert or product label for appropriate consumer-specific information about this product when used according to the physician's directions.

Hygiene measures: This SDS is for a pharmaceutical agent - Handling of this product in its final form presents minimal occupational exposure risk. In an occupational setting, handle in accordance with good industrial hygiene and safety procedures. Avoid contact with eyes, skin and clothing. Avoid breathing vapor, mist, or dust. Use appropriate personal protective equipment when handling and observe good personal hygiene measures after handling.

Conditions For Safe Storage, Including Any Incompatibilities

Storage conditions: Store in a dry, cool place. Protect from light. Store locked up

Storage temperature: 20-25°C (68-77°F)

Special rules on packaging: STERILE DILUENT: Examine the vial for particulate matter and discoloration prior to administration. If the solution is discolored or contains solid particles (precipitate), do not use.

Specific End Use(s)

Pharmaceutical. Cancer chemotherapy agent. Refer to product insert for usage instructions and product information.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

MELPHALAN HYDROCHLORIDE (lyophilized powder)

Control Parameters

No Occupational Exposure Limits (OELs) have been established for this product or its chemical components.

Exposure Controls

Appropriate engineering controls: Not generally required. Site-specific risk assessments should be conducted to determine the appropriate exposure control measures. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits.

Personal protective equipment: Safety glasses. Dust formation: dust mask. Gloves. Protective clothing.

Hand protection: Wear protective gloves made from PVC, neoprene, nitrile, vinyl, or PVC/NBR.

Eye protection: In laboratory, medical or industrial settings, or operations in which airborne particulates will be generated, safety glasses with side shields are recommended.

Skin and body protection: In laboratory, medical or industrial settings, impervious disposable gloves and protective clothing are recommended if skin contact with drug product is possible.

Respiratory protection: When manufacturing or handling product in large quantities and dusts or particulates may be generated, maintain airborne concentrations below recommended limits. Workplace risk assessments should be completed before specifying and implementing respirator usage. NIOSH/MSHA approved respirators for protection should be used if respirators are found to be necessary.

STERILE DILUENT

Control Parameters

1,2-Propylene glycol (57-55-6)		
Ontario	OEL TWA (mg/m ³)	155 mg/m ³
Ontario	OEL TWA (ppm)	50 ppm
Ethyl alcohol (64-17-5)		
USA ACGIH	ACGIH STEL (ppm)	1000 ppm
USA OSHA	OSHA PEL (TWA) (mg/m ³)	1900 mg/m ³
USA OSHA	OSHA PEL (TWA) (ppm)	1000 ppm
USA NIOSH	NIOSH REL (TWA) (mg/m ³)	1900 mg/m ³
USA NIOSH	NIOSH REL (TWA) (ppm)	1000 ppm
USA IDLH	US IDLH (ppm)	3300 ppm (10% LEL)
Alberta	OEL TWA (mg/m ³)	1880 mg/m ³
Alberta	OEL TWA (ppm)	1000 ppm
British Columbia	OEL STEL (ppm)	1000 ppm
Manitoba	OEL STEL (ppm)	1000 ppm
New Brunswick	OEL TWA (mg/m ³)	1880 mg/m ³
New Brunswick	OEL TWA (ppm)	1000 ppm
Newfoundland & Labrador	OEL STEL (ppm)	1000 ppm
Nova Scotia	OEL STEL (ppm)	1000 ppm
Nunavut	OEL STEL (mg/m ³)	2355 mg/m ³
Nunavut	OEL STEL (ppm)	1250 ppm
Nunavut	OEL TWA (mg/m ³)	1884 mg/m ³
Nunavut	OEL TWA (ppm)	1000 ppm
Northwest Territories	OEL STEL (mg/m ³)	2355 mg/m ³
Northwest Territories	OEL STEL (ppm)	1250 ppm
Northwest Territories	OEL TWA (mg/m ³)	1884 mg/m ³
Northwest Territories	OEL TWA (ppm)	1000 ppm
Ontario	OEL STEL (ppm)	1000 ppm
Prince Edward Island	OEL STEL (ppm)	1000 ppm
Québec	VEMP (mg/m ³)	1880 mg/m ³
Québec	VEMP (ppm)	1000 ppm
Saskatchewan	OEL STEL (ppm)	1250 ppm
Saskatchewan	OEL TWA (ppm)	1000 ppm
Yukon	OEL STEL (mg/m ³)	1900 mg/m ³
Yukon	OEL STEL (ppm)	1000 ppm
Yukon	OEL TWA (mg/m ³)	1900 mg/m ³
Yukon	OEL TWA (ppm)	1000 ppm

Exposure Controls

Appropriate engineering controls: Not generally required. Site-specific risk assessments should be conducted to determine the appropriate exposure control measures. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits.

Personal protective equipment: Gloves. Splash hazard: safety glasses. Mist formation: aerosol mask. Protective clothing.

Hand protection: Wear chemically resistant protective gloves.

Eye protection: In laboratory, medical or industrial settings, or operations in which airborne particulates will be generated, safety glasses with side shields are recommended.

Skin and body protection: In laboratory, medical or industrial settings, impervious disposable gloves and protective clothing are recommended if skin contact with drug product is possible.

Respiratory protection: When manufacturing or handling product in large quantities and dusts or particulates may be generated, maintain airborne concentrations below recommended limits. Workplace risk assessments should be completed before specifying and implementing respirator usage. NIOSH/MSHA approved respirators for protection should be used if respirators are found to be necessary.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information On Basic Physical And Chemical Properties

	MELPHALAN HYDROCHLORIDE	STERILE DILUENT
Physical state	Solid	Liquid
Appearance	White or nearly white lyophilized powder	Clear, colorless
Odor	Not available	Not available
Odor threshold	Not available	Not available
pH	Not available	Not available
Relative evaporation rate (butyl acetate=1)	Not available	Not available
Melting/Freezing point	Not available	Not available
Boiling point	Not available	Not available
Flash point	Not available	Not available
Auto-ignition temperature	Not available	Not available
Decomposition Temperature	Not available	Not available
Flammability (solid, gas)	Not available	Not available
Upper/Lower flammable limit	Not available	Not available
Vapor pressure	Not available	Not available
Relative vapor density at 20 °C	Not available	Not available
Relative density	Not available	Not available
Specific gravity	Not available	Not available
Solubility	Practically insoluble	Soluble in water
Log Pow/Kow	Not available	Not available
Viscosity	Not available	Not available
Explosion data - sensitivity to mechanical impact	Not available	Not available
Explosion data - sensitivity to static discharge	Not available	Not available

10. STABILITY AND REACTIVITY

Unless otherwise specified, this section applies to both Sterile Diluent and Melphalan Hydrochloride (lyophilized powder).

Reactivity Hazardous reactions will not occur under normal conditions.

Chemical Stability Stable under normal conditions.

Possibility Of Hazardous Reactions Hazardous polymerization will not occur.

Conditions To Avoid Direct sunlight. Extremely high or low temperatures.

Incompatible Materials Strong acids. Strong oxidizers. Strong bases.

Hazardous Decomposition Products Carbon oxides (CO, CO₂). MELPHALAN HYDROCHLORIDE: Nitrogen oxides. Hydrogen chloride. Hydrogen cyanide

11. TOXICOLOGICAL INFORMATION

MELPHALAN HYDROCHLORIDE (lyophilized powder)

Information on Toxicological Effects - Product

Acute toxicity: Fatal if swallowed. Fatal in contact with skin. Fatal if inhaled.

LD50 and LC50 Data: Not available

Skin Corrosion/Irritation: Not classified

Serious Eye Damage/Irritation: Not classified

Respiratory or Skin Sensitization: Not classified

Germ Cell Mutagenicity: May cause genetic defects. May cause genetic defects

Teratogenicity: Not available

Carcinogenicity: May cause cancer.

Specific Target Organ Toxicity (Repeated Exposure): Not classified

Reproductive Toxicity: Suspected of damaging fertility or the unborn child.

Specific Target Organ Toxicity (Single Exposure): Not classified

Aspiration Hazard: Not classified

Information On Toxicological Effects - Ingredient(s)

LD50 and LC50 Data

Melphalan hydrochloride (3223-07-2)	
IARC group	1

STERILE DILUENT

Information On Toxicological Effects - Product

Acute toxicity: Not classified

LD50 and LC50 Data: Not available

Skin corrosion/irritation: Causes skin irritation.

Serious eye damage/irritation: Causes eye irritation.

Respiratory or skin sensitization: Not classified

Germ cell mutagenicity: Not classified

Teratogenicity: Not available

Carcinogenicity: Not classified.

Specific target organ toxicity (repeated exposure): Not classified

Reproductive toxicity: Not classified

Specific target organ toxicity (single exposure): Not classified

Aspiration hazard: Not classified

Information On Toxicological Effects - Ingredient(s)

LD50 and LC50 Data

1,2-Propylene glycol (57-55-6)	
LD50 oral rat	20000 mg/kg
LD50 dermal rabbit	20800 mg/kg
ATE (oral)	20000 mg/kg
ATE (dermal)	20800 mg/kg
Ethyl alcohol (64-17-5)	
LD50 oral rat	7060 mg/kg
LC50 inhalation rat (mg/l)	124.7 mg/l (Exposure time: 4 h)
ATE (oral)	7060 mg/kg
ATE (dust, mist)	124.7 mg/l/4h
Ethyl alcohol (64-17-5)	
IARC group	1 (through inhalation of inorganic acid mists)

12. ECOLOGICAL INFORMATION

MELPHALAN HYDROCHLORIDE (lyophilized powder)

Toxicity Not available

Persistence And Degradability Not available

Bioaccumulative Potential Not available

STERILE DILUENT

Toxicity

1,2-Propylene glycol (57-55-6)	
LC50 fish 1	51600 mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])
EC50 Daphnia 1	> 10000 mg/l (Exposure time: 24 h - Species: Daphnia magna)
EC50 other aquatic organisms 1	19000 mg/l (Exposure time: 96 h - Species: Pseudokirchneriella subcapitata)
LC50 fish 2	41 (41 - 47) ml/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])
EC50 Daphnia 2	> 1000 mg/l (Exposure time: 48 h - Species: Daphnia magna [Static])
Ethyl alcohol (64-17-5)	
LC50 fish 1	9.5 (9.468 - 12.624) mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static]) converted from ml/l
EC50 Daphnia 1	9268 - 14221 mg/l (Exposure time: 48 h - Species: Daphnia magna)
LC50 fish 2	> 100 mg/l (Exposure time: 96 h - Species: Pimephales promelas [static])
EC50 Daphnia 2	10800 mg/l (Exposure time: 24 h - Species: Daphnia magna)

Persistence And Degradability

Ethyl alcohol (64-17-5)	
Persistence and degradability	Not established.

Bioaccumulative Potential

1,2-Propylene glycol (57-55-6)	
BCF fish 1	< 1

Ethyl alcohol (64-17-5)	
Log Pow	-0.32
Bioaccumulative potential	Not established.

13. DISPOSAL CONSIDERATIONS

Unless otherwise specified, this section applies to both Sterile Diluent and Melphalan Hydrochloride (lyophilized powder).

Waste disposal recommendations: Dispose of waste material in accordance with all local, regional, national, provincial, territorial and international regulations. Do not dispose of waste into sewer.

Additional information: Contaminated sharps should be discarded immediately or as soon as possible in containers that are closable, puncture-resistant, leak proof on sides and bottoms, and appropriately labeled. Contact your local health department for referral to a Safe Syringe Disposal Program.

14. TRANSPORT INFORMATION

In Accordance With ICAO/IATA/DOT/TDG

UN Number

UN-No.(DOT): 3249

UN Proper Shipping Name

DOT Proper Shipping Name : Medicine, solid, toxic, n.o.s. (Melphalan Hydrochloride for Injection)

Department of Transportation (DOT) Hazard : 6.1 - Class 6.1 - Poisonous materials 49 CFR 173.132

Classes

Hazard labels (DOT) : 6.1 - Poison inhalation hazard



Packing group (DOT) : II - Medium Danger

DOT Special Provisions (49 CFR 172.102) : T3 - 2.65 178.274(d)(2) Normal..... 178.275(d)(2)

TP33 - The portable tank instruction assigned for this substance applies for granular and powdered solids and for solids which are filled and discharged at temperatures above their melting point which are cooled and transported as a solid mass. Solid substances transported or offered for transport above their melting point are authorized for transportation in portable tanks conforming to the provisions of portable tank instruction T4 for solid substances of packing group III or T7 for solid substances of packing group II, unless a tank with more stringent requirements for minimum shell thickness, maximum allowable working pressure, pressure-relief devices or bottom outlets are assigned in which case the more stringent tank instruction and special provisions shall apply. Filling limits must be in accordance with portable tank special provision TP3. Solids meeting the definition of an elevated temperature material must be transported in accordance with the applicable requirements of this subchapter.

DOT Packaging Exceptions (49 CFR 173.xxx) : 153

DOT Packaging Non Bulk (49 CFR 173.xxx) : 212

DOT Packaging Bulk (49 CFR 173.xxx) : None

Additional information

Emergency Response Guide (ERG) Number : 151

Transport by sea

DOT Vessel Stowage Location : C - The material must be stowed "on deck only" on a cargo vessel and on a passenger vessel.

DOT Vessel Stowage Other : 40 - Stow "clear of living quarters"

Air transport

DOT Quantity Limitations Passenger aircraft/rail (49 CFR 173.27) : 25 kg

DOT Quantity Limitations Cargo aircraft only (49 CFR 175.75) : 100 kg

15. REGULATORY INFORMATION

US Federal regulations- MELPHALAN HYDROCHLORIDE (lyophilized powder)

Not applicable

US Federal regulations- STERILE DILUENT

1,2-Propylene glycol (57-55-6)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
EPA TSCA Regulatory Flag	Y2 - Y2 - indicates an exempt polymer that is a polyester and is made only from reactants included in a specified list of low concern reactants that comprises one of the eligibility criteria for the exemption rule.

Ethyl alcohol (64-17-5)
Listed on the United States TSCA (Toxic Substances Control Act) inventory

US State regulations- MELPHALAN HYDROCHLORIDE (lyophilized powder)

Not applicable

US State regulations- STERILE DILUENT

Ethyl alcohol (64-17-5)	
U.S. - California - Proposition 65 - Carcinogens List	WARNING: This product contains chemicals known to the State of California to cause cancer.
U.S. - California - Proposition 65 - Developmental Toxicity	WARNING: This product contains chemicals known to the State of California to cause birth defects.

1,2-Propylene glycol (57-55-6)

U.S. - New Jersey - Right to Know Hazardous Substance List

U.S. - Pennsylvania - RTK (Right to Know) List

Ethyl alcohol (64-17-5)

U.S. - Massachusetts - Allowable Ambient Limits (AALs)

U.S. - Massachusetts - Allowable Threshold Concentrations (ATCs)

U.S. - Massachusetts - Oil & Hazardous Material List - Groundwater Reportable Concentration - Reporting Category 1

U.S. - Massachusetts - Oil & Hazardous Material List - Groundwater Reportable Concentration - Reporting Category 2

U.S. - Massachusetts - Oil & Hazardous Material List - Reportable Quantity

U.S. - Massachusetts - Oil & Hazardous Material List - Soil Reportable Concentration - Reporting Category 1

U.S. - Massachusetts - Oil & Hazardous Material List - Soil Reportable Concentration - Reporting Category 2

U.S. - Massachusetts - Right To Know List

U.S. - Massachusetts - Threshold Effects Exposure Limits (TELEs)

U.S. - New Jersey - Right to Know Hazardous Substance List

U.S. - New Jersey - Special Health Hazards Substances List

U.S. - New York - Occupational Exposure Limits - TWAs

U.S. - Pennsylvania - RTK (Right to Know) List

Canadian regulations- MELPHALAN HYDROCHLORIDE (lyophilized powder)

Melphalan Hydrochloride for Injection

WHMIS Classification	Class D Division 2 Subdivision A - Very toxic material causing other toxic effects Class D Division 2 Subdivision B - Toxic material causing other toxic effects
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Melphalan hydrochloride (3223-07-2)

WHMIS Classification	Class D Division 2 Subdivision A - Very toxic material causing other toxic effects Class D Division 2 Subdivision B - Toxic material causing other toxic effects
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This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations (CPR) and the MSDS contains all of the information required by CPR.

Canadian regulations- STERILE DILUENT

Sterile Diluent (for Melphalan Hydrochloride)

WHMIS Classification	Class B Division 2 - Flammable Liquid Class D Division 2 Subdivision B - Toxic material causing other toxic effects
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1,2-Propylene glycol (57-55-6)

Listed on the Canadian DSL (Domestic Substances List) inventory.

Listed on the Canadian Ingredient Disclosure List

WHMIS Classification	Uncontrolled product according to WHMIS classification criteria
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Ethyl alcohol (64-17-5)

Listed on the Canadian DSL (Domestic Substances List) inventory.

Listed on the Canadian Ingredient Disclosure List

WHMIS Classification	Class B Division 2 - Flammable Liquid Class D Division 2 Subdivision B - Toxic material causing other toxic effects
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This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations (CPR) and the MSDS contains all of the information required by CPR.

16.	OTHER INFORMATION
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Indication of Changes : 02/10/2014
Data sources : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200.
Other information : This document has been prepared in accordance with standards for workplace safety. The precautionary statements and warnings included might not apply in all cases. Your needs may vary depending on the potential for exposure in your workplace.

GHS Full Text Phrases: MELPHALAN HYDROCHLORIDE (lyophilized powder)

Acute Tox. 1 (Dermal)	Acute toxicity (dermal) Category 1
Acute Tox. 1 (Oral)	Acute toxicity (oral) Category 1
Acute Tox. 2 (Inhalation:dust,mist)	Acute toxicity (inhalation:dust,mist) Category 2
Carc. 1A	Carcinogenicity Category 1A
Comb. Dust	Combustible Dust
Muta. 1B	Germ cell mutagenicity Category 1B
Repr. 2	Reproductive toxicity Category 2
H232	May form combustible dust concentrations in air
H300	Fatal if swallowed
H310	Fatal in contact with skin
H330	Fatal if inhaled
H340	May cause genetic defects
H350	May cause cancer
H361	Suspected of damaging fertility or the unborn child

GHS Full Text Phrases: STERILE DILUENT

Eye Irrit. 2A	Serious eye damage/eye irritation Category 2A
Eye Irrit. 2B	Serious eye damage/eye irritation Category 2B
Flam. Liq. 2	Flammable liquids Category 2
Flam. Liq. 3	Flammable liquids Category 3
Skin Irrit. 2	Skin corrosion/irritation Category 2
H225	Highly flammable liquid and vapor
H226	Flammable liquid and vapor
H315	Causes skin irritation
H319	Causes serious eye irritation

Party Responsible For The Preparation Of This Document:

Mylan Global Environmental, Health, and Safety Department
Phone Number: 304-599-2595

This MSDS has been prepared for occupational exposure and intended to address some end-user concerns; however, patients/consumers are also strongly encouraged to review the product information insert or product label for consumer-specific information about this product. Patients/Consumers: Refer to the package insert or product label for appropriate consumer-specific information about this product when used according to manufacturer's directions.

To the best of our knowledge, the information contained herein is accurate. However, neither the above named supplier nor any of its subsidiaries assumes any liability whatsoever for completeness of the information herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

North America Mylan Pharmaceuticals



MELPHALAN HYDROCHLORIDE FOR INJECTION

SAFETY DATA SHEET

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY

Product Identifier

Product name: Melphalan Hydrochloride for Injection

Intended Use Of The Product

Use of the substance/preparation: Pharmaceutical. Cancer chemotherapy agent. Powdered form of Melphalan is supplied with a sterile diluent intended to be added prior to administration. Use only as directed. Refer to product insert for usage instructions and product information.

Name, Address, And Telephone Of The Responsible Party

Supplier:

Mylan Institutional LLC
1718 Northrock Court
Rockford, IL 61003 USA
800.848.0462

www.mylan.com

Manufacturer:

Mylan Teoranta
Galway, Ireland

Emergency Telephone Number

Emergency number : +1 877-446-3679

2. HAZARDS IDENTIFICATION

Patients/Consumers: Please refer to the product information insert or product label for appropriate consumer-specific information about this product when used according to the physician's directions. Pharmaceutical Agent – Handling of this product in its final form presents minimal occupational exposure risk.

MELPHALAN HYDROCHLORIDE (lyophilized powder)

Classification of the Substance or Mixture

Classification (GHS-US)

Acute Tox. 1 (Oral)	H300
Acute Tox. 1 (Dermal)	H310
Acute Tox. 2 (Inhalation:dust,mist)	H330
Muta. 1B	H340
Carc. 1A	H350
Repr. 2	H361

Label Elements

GHS-US labeling

Hazard pictograms (GHS-US) :



Signal word (GHS-US) :

Danger

Hazard statements (GHS-US) :

H300+H310+H330 - Fatal if swallowed, in contact with skin or if inhaled
H340 - May cause genetic defects
H350 - May cause cancer
H361 - Suspected of damaging fertility or the unborn child

Precautionary statements (GHS-US) :

P201 - Obtain special instructions before use.
P202 - Do not handle until all safety precautions have been read and understood.
P260 - Do not breathe dust.
P262 - Do not get in eyes, on skin, or on clothing.
P264 - Wash hands, forearms, and exposed areas thoroughly after handling.

P270 - Do not eat, drink or smoke when using this product.
 P271 - Use only outdoors or in a well-ventilated area.
 P280 - Wear protective gloves/protective clothing/eye protection/face protection.
 P284 - Wear respiratory protection.
 P301+P310+P330 - IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician. If swallowed, rinse mouth.
 P304+P340 - IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
 P308+P313 - If exposed or concerned: Get medical advice/attention.
 P310 - Immediately call a POISON CENTER or doctor/physician.
 P361 - Remove/Take off immediately all contaminated clothing.
 P363 - Wash contaminated clothing before reuse.
 P405 - Store locked up.
 P501 - Dispose of contents/container according to local, regional, national, provincial, territorial, and international regulations.

Other Hazards Not available

Unknown acute toxicity (GHS US) Not available

STERILE DILUENT

Classification Of The Substance Or Mixture

Classification (GHS-US)

Flam. Liq. 2 H225
 Skin Irrit. 2 H315
 Eye Irrit. 2B H320

Label Elements

GHS-US labeling

Hazard pictograms (GHS-US)



Signal word (GHS-US)

: Danger

Hazard statements (GHS-US)

: H225 - Highly flammable liquid and vapor
 H315 - Causes skin irritation
 H320 - Causes eye irritation

Precautionary statements (GHS-US)

: P210 - Keep away from heat/sparks/open flames/hot surfaces. - No smoking.
 P233 - Keep container tightly closed.
 P240 - Ground/bond container and receiving equipment.
 P241 - Use explosion-proof electrical/ventilating/lighting equipment.
 P242 - Use only non-sparking tools.
 P243 - Take precautionary measures against static discharge.
 P264 - Wash hands, forearms, and exposed areas thoroughly after handling.
 P280 - Wear protective gloves/protective clothing/eye protection/face protection.
 P303+P361+P353 - IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.
 P305+P351+P338 - If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
 P332+P313 - If skin irritation occurs: get medical advice/attention.
 P337+P313 - If eye irritation persists: get medical advice/attention.
 P362 - Take off contaminated clothing.
 P370+P378 - In case of fire: Use appropriate media for extinction.
 P403+P235 - Store in a well-ventilated place. Keep cool.
 P501 - Dispose of contents/container according to local, regional, national, territorial, provincial, and international regulations.

Other Hazards Not available

Unknown acute toxicity (GHS US) Not available

3. COMPOSITION/INFORMATION ON INGREDIENTS

MELPHALAN HYDROCHLORIDE (lyophilized powder)

Mixture

Name	Product identifier	% (w/w)	Classification (GHS-US)
Melphalan hydrochloride	(CAS No.) 3223-07-2	71.4	Acute Tox. 1 (Oral), H300

			Acute Tox. 1 (Dermal), H310 Acute Tox. 2 (Inhalation:dust,mist), H330 Muta. 1B, H340 Carc. 1A, H350 Repr. 2, H361
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Full text of H-phrases: see section 16

STERILE DILUENT

Mixture

Name	Product identifier	% (w/w)	Classification (GHS-US)
1,2-Propylene glycol	(CAS No.) 57-55-6	61	Flam. Liq. 3, H226 Skin Irrit. 2, H315 Eye Irrit. 2B, H320
Ethyl alcohol	(CAS No.) 64-17-5	4	Flam. Liq. 2, H225 Skin Irrit. 2, H315 Eye Irrit. 2A, H319

Full text of H-phrases: see section 16

4. FIRST AID MEASURES

Description Of First Aid Measures- Sterile Diluent and Melphalan Hydrochloride (lyophilized powder).

General: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show label if possible).

Inhalation: The risk of inhalation exposure is negligible when product is in its final packaged form. If exposed and become symptomatic, move to fresh air and get medical attention if symptoms persist.

Skin Contact: Basic hygiene and appropriate precautions should prevent skin contact. If skin contact occurs, wash affected area with soap and water for at least 15 minutes. Should skin irritation, allergic reaction, or rash occur, remove contaminated clothing (if required) and seek medical advice.

Eye Contact: The risk of eye exposure is negligible when product is in its final packaged form. If eye contact occurs, flush immediately with water for at least 15 minutes. If easy to do, remove contact lenses. Get medical attention.

Ingestion: Ingestion is not an anticipated route of exposure. If accidental ingestion occurs, flush mouth out with water and get medical attention.

MELPHALAN HYDROCHLORIDE (lyophilized powder)

Most Important Symptoms And Effects Both Acute and Delayed

General: The most common side effects include nausea, vomiting, diarrhea, temporary hair loss, skin rash. More severe side effects include fever, chills, body aches, bruising, dark colored urine, pale or yellowed skin.

Inhalation: Fatal if inhaled.

Skin Contact: Fatal in contact with skin.

Eye Contact: Direct contact with the eyes is likely irritating.

Ingestion: Fatal if swallowed.

Chronic symptoms: May cause cancer. May cause heritable genetic damage. May damage fertility or the unborn child.

Indication Of Any Immediate Medical Attention And Special Treatment Needed

If exposed or concerned, get medical advice and attention.

STERILE DILUENT

Most Important Symptoms And Effects Both Acute and Delayed

General: Irritation to eyes, skin and respiratory tract.

Inhalation: May be irritating to the respiratory tract.

Skin Contact: Causes mild skin irritation.

Eye Contact: Causes eye irritation.

Ingestion: May cause headache, nausea, dizziness, drowsiness, and loss of coordination.

Chronic symptoms: Chronic exposure may cause liver and kidney damage.

Indication Of Any Immediate Medical Attention And Special Treatment Needed

If exposed or concerned, get medical advice and attention. In the event of accidental injection, go immediately to the nearest emergency room.

5. FIREFIGHTING MEASURES

MELPHALAN HYDROCHLORIDE (lyophilized powder)

Extinguishing Media

Suitable extinguishing media: Not flammable. Use extinguishing media appropriate for surrounding fire.

Unsuitable extinguishing media: None known.

Special Hazards Arising From The Substance Or Mixture

Fire hazard: Not flammable

Explosion hazard: Product is not explosive

Reactivity: Hazardous reactions will not occur under normal conditions.

Advice For Firefighters

Firefighting Instructions: Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Do not allow run-off from fire fighting to enter drains or water courses.

Protection during firefighting: Do not enter fire area without proper protective equipment, including respiratory protection.

Hazardous Combustion Products: Carbon oxides (CO, CO₂). Nitrogen oxides. Hydrogen chloride. Hydrogen cyanide.

Other information: Refer to Section 9 for flammability properties.

STERILE DILUENT

Extinguishing Media

Suitable extinguishing media: Dry chemical powder, alcohol-resistant foam, carbon dioxide (CO₂).

Unsuitable extinguishing media: Do not use a heavy water stream. Use of a heavy stream of water may spread fire.

Special Hazards Arising From The Substance Or Mixture

Fire hazard: Highly flammable liquid and vapor.

Explosion hazard: Heat may build pressure, rupturing closed containers and spreading fire.

Reactivity: Hazardous reactions will not occur under normal conditions.

Advice For Firefighters

Firefighting Instructions: Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Do not allow run-off from fire fighting to enter drains or water courses.

Protection during firefighting: Do not enter fire area without proper protective equipment, including respiratory protection.

Hazardous Combustion Products: Carbon oxides (CO, CO₂).

Other information: Refer to Section 9 for flammability properties.

6. ACCIDENTAL RELEASE MEASURES

Unless otherwise specified, this section applies to both Sterile Diluent and Melphalan Hydrochloride (lyophilized powder).

Personal Precautions, Protective Equipment And Emergency Procedures

General measures: MELPHALAN HYDROCHLORIDE: Do not breathe dust. Do not get in eyes, on skin, or on clothing.

STERILE DILUENT: Avoid all eye and skin contact and do not breathe vapor or mist. Keep away from heat/sparks/open flames/hot surfaces – No smoking.

For Non-Emergency Personnel

Protective equipment: Use appropriate personal protection equipment (PPE).

Emergency procedures: Evacuate unnecessary personnel. Eliminate ignition sources.

For Emergency Personnel

Protective equipment: Use appropriate personal protection equipment (PPE).

Emergency procedures: If possible, stop flow of product. Ventilate area.

Environmental Precautions

Prevent entry to sewers and public waters.

Methods And Material For Containment And Cleaning Up

Methods for cleaning up: For small quantities associated with normal therapeutic use, collect spillage and transfer to a closed waste container for disposal. For large or bulk quantities, after absorption with inert material, collect spillage by sweeping up spilled material and place in a labeled, sealed container for proper disposal.

Reference To Other Sections

See heading 8, Exposure Controls and Personal Protection.

7. HANDLING AND STORAGE

Unless otherwise specified, this section applies to both Sterile Diluent and Melphalan Hydrochloride (lyophilized powder).

Precautions For Safe Handling

Patients/Consumers: Patients should adhere to the instructions provided within the product information insert or product label for appropriate consumer-specific information about this product when used according to the physician's directions.

Hygiene measures: This SDS is for a pharmaceutical agent - Handling of this product in its final form presents minimal occupational exposure risk. In an occupational setting, handle in accordance with good industrial hygiene and safety procedures. Avoid contact with eyes, skin and clothing. Avoid breathing vapor, mist, or dust. Use appropriate personal protective equipment when handling and observe good personal hygiene measures after handling.

Conditions For Safe Storage, Including Any Incompatibilities

Storage conditions: Store in a dry, cool place. Protect from light. Store locked up

Storage temperature: 20-25°C (68-77°F)

Special rules on packaging: STERILE DILUENT: Examine the vial for particulate matter and discoloration prior to administration. If the solution is discolored or contains solid particles (precipitate), do not use.

Specific End Use(s)

Pharmaceutical. Cancer chemotherapy agent. Refer to product insert for usage instructions and product information.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

MELPHALAN HYDROCHLORIDE (lyophilized powder)

Control Parameters

No Occupational Exposure Limits (OELs) have been established for this product or its chemical components.

Exposure Controls

Appropriate engineering controls: Not generally required. Site-specific risk assessments should be conducted to determine the appropriate exposure control measures. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits.

Personal protective equipment: Safety glasses. Dust formation: dust mask. Gloves. Protective clothing.

Hand protection: Wear protective gloves made from PVC, neoprene, nitrile, vinyl, or PVC/NBR.

Eye protection: In laboratory, medical or industrial settings, or operations in which airborne particulates will be generated, safety glasses with side shields are recommended.

Skin and body protection: In laboratory, medical or industrial settings, impervious disposable gloves and protective clothing are recommended if skin contact with drug product is possible.

Respiratory protection: When manufacturing or handling product in large quantities and dusts or particulates may be generated, maintain airborne concentrations below recommended limits. Workplace risk assessments should be completed before specifying and implementing respirator usage. NIOSH/MSHA approved respirators for protection should be used if respirators are found to be necessary.

STERILE DILUENT

Control Parameters

1,2-Propylene glycol (57-55-6)		
Ontario	OEL TWA (mg/m ³)	155 mg/m ³
Ontario	OEL TWA (ppm)	50 ppm
Ethyl alcohol (64-17-5)		
USA ACGIH	ACGIH STEL (ppm)	1000 ppm
USA OSHA	OSHA PEL (TWA) (mg/m ³)	1900 mg/m ³
USA OSHA	OSHA PEL (TWA) (ppm)	1000 ppm
USA NIOSH	NIOSH REL (TWA) (mg/m ³)	1900 mg/m ³
USA NIOSH	NIOSH REL (TWA) (ppm)	1000 ppm
USA IDLH	US IDLH (ppm)	3300 ppm (10% LEL)
Alberta	OEL TWA (mg/m ³)	1880 mg/m ³
Alberta	OEL TWA (ppm)	1000 ppm
British Columbia	OEL STEL (ppm)	1000 ppm
Manitoba	OEL STEL (ppm)	1000 ppm
New Brunswick	OEL TWA (mg/m ³)	1880 mg/m ³
New Brunswick	OEL TWA (ppm)	1000 ppm
Newfoundland & Labrador	OEL STEL (ppm)	1000 ppm
Nova Scotia	OEL STEL (ppm)	1000 ppm
Nunavut	OEL STEL (mg/m ³)	2355 mg/m ³
Nunavut	OEL STEL (ppm)	1250 ppm
Nunavut	OEL TWA (mg/m ³)	1884 mg/m ³
Nunavut	OEL TWA (ppm)	1000 ppm
Northwest Territories	OEL STEL (mg/m ³)	2355 mg/m ³
Northwest Territories	OEL STEL (ppm)	1250 ppm
Northwest Territories	OEL TWA (mg/m ³)	1884 mg/m ³
Northwest Territories	OEL TWA (ppm)	1000 ppm
Ontario	OEL STEL (ppm)	1000 ppm
Prince Edward Island	OEL STEL (ppm)	1000 ppm
Québec	VEMP (mg/m ³)	1880 mg/m ³
Québec	VEMP (ppm)	1000 ppm
Saskatchewan	OEL STEL (ppm)	1250 ppm
Saskatchewan	OEL TWA (ppm)	1000 ppm
Yukon	OEL STEL (mg/m ³)	1900 mg/m ³
Yukon	OEL STEL (ppm)	1000 ppm
Yukon	OEL TWA (mg/m ³)	1900 mg/m ³
Yukon	OEL TWA (ppm)	1000 ppm

Exposure Controls

Appropriate engineering controls: Not generally required. Site-specific risk assessments should be conducted to determine the appropriate exposure control measures. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits.

Personal protective equipment: Gloves. Splash hazard: safety glasses. Mist formation: aerosol mask. Protective clothing.

Hand protection: Wear chemically resistant protective gloves.

Eye protection: In laboratory, medical or industrial settings, or operations in which airborne particulates will be generated, safety glasses with side shields are recommended.

Skin and body protection: In laboratory, medical or industrial settings, impervious disposable gloves and protective clothing are recommended if skin contact with drug product is possible.

Respiratory protection: When manufacturing or handling product in large quantities and dusts or particulates may be generated, maintain airborne concentrations below recommended limits. Workplace risk assessments should be completed before specifying and implementing respirator usage. NIOSH/MSHA approved respirators for protection should be used if respirators are found to be necessary.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information On Basic Physical And Chemical Properties

	MELPHALAN HYDROCHLORIDE	STERILE DILUENT
Physical state	Solid	Liquid
Appearance	White or nearly white lyophilized powder	Clear, colorless
Odor	Not available	Not available
Odor threshold	Not available	Not available
pH	Not available	Not available
Relative evaporation rate (butyl acetate=1)	Not available	Not available
Melting/Freezing point	Not available	Not available
Boiling point	Not available	Not available
Flash point	Not available	Not available
Auto-ignition temperature	Not available	Not available
Decomposition Temperature	Not available	Not available
Flammability (solid, gas)	Not available	Not available
Upper/Lower flammable limit	Not available	Not available
Vapor pressure	Not available	Not available
Relative vapor density at 20 °C	Not available	Not available
Relative density	Not available	Not available
Specific gravity	Not available	Not available
Solubility	Practically insoluble	Soluble in water
Log Pow/Kow	Not available	Not available
Viscosity	Not available	Not available
Explosion data - sensitivity to mechanical impact	Not available	Not available
Explosion data - sensitivity to static discharge	Not available	Not available

10. STABILITY AND REACTIVITY

Unless otherwise specified, this section applies to both Sterile Diluent and Melphalan Hydrochloride (lyophilized powder).

Reactivity Hazardous reactions will not occur under normal conditions.

Chemical Stability Stable under normal conditions.

Possibility Of Hazardous Reactions Hazardous polymerization will not occur.

Conditions To Avoid Direct sunlight. Extremely high or low temperatures.

Incompatible Materials Strong acids. Strong oxidizers. Strong bases.

Hazardous Decomposition Products Carbon oxides (CO, CO₂). MELPHALAN HYDROCHLORIDE: Nitrogen oxides. Hydrogen chloride. Hydrogen cyanide

11. TOXICOLOGICAL INFORMATION

MELPHALAN HYDROCHLORIDE (lyophilized powder)

Information on Toxicological Effects - Product

Acute toxicity: Fatal if swallowed. Fatal in contact with skin. Fatal if inhaled.

LD50 and LC50 Data: Not available

Skin Corrosion/Irritation: Not classified

Serious Eye Damage/Irritation: Not classified

Respiratory or Skin Sensitization: Not classified

Germ Cell Mutagenicity: May cause genetic defects. May cause genetic defects

Teratogenicity: Not available

Carcinogenicity: May cause cancer.

Specific Target Organ Toxicity (Repeated Exposure): Not classified

Reproductive Toxicity: Suspected of damaging fertility or the unborn child.

Specific Target Organ Toxicity (Single Exposure): Not classified

Aspiration Hazard: Not classified

Information On Toxicological Effects - Ingredient(s)

LD50 and LC50 Data

Melphalan hydrochloride (3223-07-2)	
IARC group	1

STERILE DILUENT

Information On Toxicological Effects - Product

Acute toxicity: Not classified

LD50 and LC50 Data: Not available

Skin corrosion/irritation: Causes skin irritation.

Serious eye damage/irritation: Causes eye irritation.

Respiratory or skin sensitization: Not classified

Germ cell mutagenicity: Not classified

Teratogenicity: Not available

Carcinogenicity: Not classified.

Specific target organ toxicity (repeated exposure): Not classified

Reproductive toxicity: Not classified

Specific target organ toxicity (single exposure): Not classified

Aspiration hazard: Not classified

Information On Toxicological Effects - Ingredient(s)

LD50 and LC50 Data

1,2-Propylene glycol (57-55-6)	
LD50 oral rat	20000 mg/kg
LD50 dermal rabbit	20800 mg/kg
ATE (oral)	20000 mg/kg
ATE (dermal)	20800 mg/kg
Ethyl alcohol (64-17-5)	
LD50 oral rat	7060 mg/kg
LC50 inhalation rat (mg/l)	124.7 mg/l (Exposure time: 4 h)
ATE (oral)	7060 mg/kg
ATE (dust, mist)	124.7 mg/l/4h
Ethyl alcohol (64-17-5)	
IARC group	1 (through inhalation of inorganic acid mists)

12. ECOLOGICAL INFORMATION

MELPHALAN HYDROCHLORIDE (lyophilized powder)

Toxicity Not available

Persistence And Degradability Not available

Bioaccumulative Potential Not available

STERILE DILUENT

Toxicity

1,2-Propylene glycol (57-55-6)	
LC50 fish 1	51600 mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])
EC50 Daphnia 1	> 10000 mg/l (Exposure time: 24 h - Species: Daphnia magna)
EC50 other aquatic organisms 1	19000 mg/l (Exposure time: 96 h - Species: Pseudokirchneriella subcapitata)
LC50 fish 2	41 (41 - 47) ml/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])
EC50 Daphnia 2	> 1000 mg/l (Exposure time: 48 h - Species: Daphnia magna [Static])
Ethyl alcohol (64-17-5)	
LC50 fish 1	9.5 (9.468 - 12.624) mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static]) converted from ml/l
EC50 Daphnia 1	9268 - 14221 mg/l (Exposure time: 48 h - Species: Daphnia magna)
LC50 fish 2	> 100 mg/l (Exposure time: 96 h - Species: Pimephales promelas [static])
EC50 Daphnia 2	10800 mg/l (Exposure time: 24 h - Species: Daphnia magna)

Persistence And Degradability

Ethyl alcohol (64-17-5)	
Persistence and degradability	Not established.

Bioaccumulative Potential

1,2-Propylene glycol (57-55-6)	
BCF fish 1	< 1

Ethyl alcohol (64-17-5)	
Log Pow	-0.32
Bioaccumulative potential	Not established.

13. DISPOSAL CONSIDERATIONS

Unless otherwise specified, this section applies to both Sterile Diluent and Melphalan Hydrochloride (lyophilized powder).

Waste disposal recommendations: Dispose of waste material in accordance with all local, regional, national, provincial, territorial and international regulations. Do not dispose of waste into sewer.

Additional information: Contaminated sharps should be discarded immediately or as soon as possible in containers that are closable, puncture-resistant, leak proof on sides and bottoms, and appropriately labeled. Contact your local health department for referral to a Safe Syringe Disposal Program.

14. TRANSPORT INFORMATION

In Accordance With ICAO/IATA/DOT/TDG

UN Number

UN-No.(DOT): 3249

UN Proper Shipping Name

DOT Proper Shipping Name : Medicine, solid, toxic, n.o.s. (Melphalan Hydrochloride for Injection)

Department of Transportation (DOT) Hazard : 6.1 - Class 6.1 - Poisonous materials 49 CFR 173.132

Classes

Hazard labels (DOT) : 6.1 - Poison inhalation hazard



Packing group (DOT) : II - Medium Danger

DOT Special Provisions (49 CFR 172.102) : T3 - 2.65 178.274(d)(2) Normal..... 178.275(d)(2)

TP33 - The portable tank instruction assigned for this substance applies for granular and powdered solids and for solids which are filled and discharged at temperatures above their melting point which are cooled and transported as a solid mass. Solid substances transported or offered for transport above their melting point are authorized for transportation in portable tanks conforming to the provisions of portable tank instruction T4 for solid substances of packing group III or T7 for solid substances of packing group II, unless a tank with more stringent requirements for minimum shell thickness, maximum allowable working pressure, pressure-relief devices or bottom outlets are assigned in which case the more stringent tank instruction and special provisions shall apply. Filling limits must be in accordance with portable tank special provision TP3. Solids meeting the definition of an elevated temperature material must be transported in accordance with the applicable requirements of this subchapter.

DOT Packaging Exceptions (49 CFR 173.xxx) : 153

DOT Packaging Non Bulk (49 CFR 173.xxx) : 212

DOT Packaging Bulk (49 CFR 173.xxx) : None

Additional information

Emergency Response Guide (ERG) Number : 151

Transport by sea

DOT Vessel Stowage Location : C - The material must be stowed "on deck only" on a cargo vessel and on a passenger vessel.

DOT Vessel Stowage Other : 40 - Stow "clear of living quarters"

Air transport

DOT Quantity Limitations Passenger aircraft/rail (49 CFR 173.27) : 25 kg

DOT Quantity Limitations Cargo aircraft only (49 CFR 175.75) : 100 kg




15. REGULATORY INFORMATION

US Federal regulations- MELPHALAN HYDROCHLORIDE (lyophilized powder)

Not applicable

US Federal regulations- STERILE DILUENT

1,2-Propylene glycol (57-55-6)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
EPA TSCA Regulatory Flag	Y2 - Y2 - indicates an exempt polymer that is a polyester and is made only from reactants included in a specified list of low concern reactants that comprises one of the eligibility criteria for the exemption rule.

Ethyl alcohol (64-17-5)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
US State regulations- MELPHALAN HYDROCHLORIDE (lyophilized powder)	
Not applicable	
US State regulations- STERILE DILUENT	
Ethyl alcohol (64-17-5)	
U.S. - California - Proposition 65 - Carcinogens List	WARNING: This product contains chemicals known to the State of California to cause cancer.
U.S. - California - Proposition 65 - Developmental Toxicity	WARNING: This product contains chemicals known to the State of California to cause birth defects.
1,2-Propylene glycol (57-55-6)	
U.S. - New Jersey - Right to Know Hazardous Substance List	
U.S. - Pennsylvania - RTK (Right to Know) List	
Ethyl alcohol (64-17-5)	
U.S. - Massachusetts - Allowable Ambient Limits (AALs)	
U.S. - Massachusetts - Allowable Threshold Concentrations (ATCs)	
U.S. - Massachusetts - Oil & Hazardous Material List - Groundwater Reportable Concentration - Reporting Category 1	
U.S. - Massachusetts - Oil & Hazardous Material List - Groundwater Reportable Concentration - Reporting Category 2	
U.S. - Massachusetts - Oil & Hazardous Material List - Reportable Quantity	
U.S. - Massachusetts - Oil & Hazardous Material List - Soil Reportable Concentration - Reporting Category 1	
U.S. - Massachusetts - Oil & Hazardous Material List - Soil Reportable Concentration - Reporting Category 2	
U.S. - Massachusetts - Right To Know List	
U.S. - Massachusetts - Threshold Effects Exposure Limits (TELEs)	
U.S. - New Jersey - Right to Know Hazardous Substance List	
U.S. - New Jersey - Special Health Hazards Substances List	
U.S. - New York - Occupational Exposure Limits - TWAs	
U.S. - Pennsylvania - RTK (Right to Know) List	
Canadian regulations- MELPHALAN HYDROCHLORIDE (lyophilized powder)	
Melphalan Hydrochloride for Injection	
WHMIS Classification	Class D Division 2 Subdivision A - Very toxic material causing other toxic effects Class D Division 2 Subdivision B - Toxic material causing other toxic effects
	
Melphalan hydrochloride (3223-07-2)	
WHMIS Classification	Class D Division 2 Subdivision A - Very toxic material causing other toxic effects Class D Division 2 Subdivision B - Toxic material causing other toxic effects
This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations (CPR) and the MSDS contains all of the information required by CPR.	
Canadian regulations- STERILE DILUENT	
Sterile Diluent (for Melphalan Hydrochloride)	
WHMIS Classification	Class B Division 2 - Flammable Liquid Class D Division 2 Subdivision B - Toxic material causing other toxic effects
 	
1,2-Propylene glycol (57-55-6)	
Listed on the Canadian DSL (Domestic Substances List) inventory.	
Listed on the Canadian Ingredient Disclosure List	
WHMIS Classification	Uncontrolled product according to WHMIS classification criteria
Ethyl alcohol (64-17-5)	
Listed on the Canadian DSL (Domestic Substances List) inventory.	
Listed on the Canadian Ingredient Disclosure List	
WHMIS Classification	Class B Division 2 - Flammable Liquid Class D Division 2 Subdivision B - Toxic material causing other toxic effects

This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations (CPR) and the MSDS contains all of the information required by CPR.

16.	OTHER INFORMATION
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Indication of Changes : 02/10/2014
Data sources : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200.
Other information : This document has been prepared in accordance with standards for workplace safety. The precautionary statements and warnings included might not apply in all cases. Your needs may vary depending on the potential for exposure in your workplace.

GHS Full Text Phrases: MELPHALAN HYDROCHLORIDE (lyophilized powder)

Acute Tox. 1 (Dermal)	Acute toxicity (dermal) Category 1
Acute Tox. 1 (Oral)	Acute toxicity (oral) Category 1
Acute Tox. 2 (Inhalation:dust,mist)	Acute toxicity (inhalation:dust,mist) Category 2
Carc. 1A	Carcinogenicity Category 1A
Comb. Dust	Combustible Dust
Muta. 1B	Germ cell mutagenicity Category 1B
Repr. 2	Reproductive toxicity Category 2
H232	May form combustible dust concentrations in air
H300	Fatal if swallowed
H310	Fatal in contact with skin
H330	Fatal if inhaled
H340	May cause genetic defects
H350	May cause cancer
H361	Suspected of damaging fertility or the unborn child

GHS Full Text Phrases: STERILE DILUENT

Eye Irrit. 2A	Serious eye damage/eye irritation Category 2A
Eye Irrit. 2B	Serious eye damage/eye irritation Category 2B
Flam. Liq. 2	Flammable liquids Category 2
Flam. Liq. 3	Flammable liquids Category 3
Skin Irrit. 2	Skin corrosion/irritation Category 2
H225	Highly flammable liquid and vapor
H226	Flammable liquid and vapor
H315	Causes skin irritation
H319	Causes serious eye irritation

Party Responsible For The Preparation Of This Document:

Mylan Global Environmental, Health, and Safety Department
 Phone Number: 304-599-2595

This MSDS has been prepared for occupational exposure and intended to address some end-user concerns; however, patients/consumers are also strongly encouraged to review the product information insert or product label for consumer-specific information about this product. Patients/Consumers: Refer to the package insert or product label for appropriate consumer-specific information about this product when used according to manufacturer's directions.

To the best of our knowledge, the information contained herein is accurate. However, neither the above named supplier nor any of its subsidiaries assumes any liability whatsoever for completeness of the information herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

North America Mylan Pharmaceuticals