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Section 1 - Identification

- (a) **Product Identifier:** Melphalan Hydrochloride for Injection
- (b) **Product Code:** 70860-212
70860-213
70860-214
- Common/Trade Name:** Melphalan
- Chemical Name(s):** 4-[bis(2-chloroethyl)amino]-L-phenylalanine
- Chemical Family:** Bifunctional alkylating agent
- (c) **Product Use:** Pharmaceutical, Injectable
- Product Type:** Regulated Prescription Drug
- Container Information:** Single Use Vial
- (d) **Distributor:** Athenex Pharmaceutical Division, 10 N. Martingale Road, Suite 230, Schaumburg, IL 60173, 847-886-9515
- (e) **Emergency Telephone:** 855-273-0154


Section 2 - Hazards Identification

- (a) **Classification:** **Physical hazards** Not classified.
- Health hazards** Acute toxicity, oral Category 2
Sensitization, respiratory Category 1
Germ cell mutagenicity Category 2
Carcinogenicity Category 1
Reproductive toxicity Category 1
Specific target organ toxicity, repeated Category 1 (bone marrow)
Exposure
- OSHA hazard(s)** Not classified.

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(b) Signal Word, Hazard statement(s), Symbol(s), and/or Precautionary statement(s):	(c) Description of Hazards:
Signal Word:	Danger
Symbol:	
Hazard Statements:	<p>Fatal if swallowed. May cause allergy or asthma symptoms or breathing difficulties if inhaled.</p> <p>Suspected of causing genetic defects. May cause cancer. May damage fertility or the unborn child. Causes damage to organs (bone marrow) through prolonged or repeated exposure.</p>
Precautionary Statements:	<p>Prevention Wash thoroughly after handling. In case of inadequate ventilation wear respiratory protection. Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Wear protective gloves/protective clothing/eye protection/face protection. Do not breathe dust.</p> <p>Response If swallowed: Immediately call a poison center/doctor. Rinse mouth. If inhaled: If breathing is difficult, remove person to fresh air and keep comfortable for breathing. If experiencing respiratory symptoms: Call a poison center/doctor. If exposed or concerned: Get medical advice/attention.</p> <p>Storage Store locked up.</p> <p>Disposal Dispose of contents/container in accordance with local/regional/national/international regulations.</p>

(d) Unknown Acute Toxicity N/A

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Section 3 – Composition / Information on Ingredients

Melphalan Hydrochloride for Injection

(a) Chemical Name	(b) Common Name / Synonym	% Composition or other measure	(c) CAS No.	(d) Impurities / Stabilizing Additives
4-[bis(2-chloroethyl)amino]-L-phenylalanine	Melphalan Hydrochloride/ L-phenylalanine mustard, phenylalanine mustard, L-PAM, or Lsarcolysin	22.38 mg (20.00 mg of Melphalan)/ mL	148-82-3	N/A
Povidone K12	Povidone K12	8.00 mg/ mL	9003-39-8	N/A
Hydrochloric Acid	Hydrochloric Acid	0.24 mL/ mL	7647-01-0	N/A
Hydrochloric Acid	Hydrochloric Acid	q.s.	7647-01-0	N/A
Water for Injection	Water for Injection	q.s. to 1 mL	7732-18-5	N/A
Nitrogen	Nitrogen	As required	7727-37-9	N/A

Diluent for Melphalan hydrochloride for Injection

(a) Chemical Name	(b) Common Name / Synonym	% Composition or other measure	(c) CAS No.	(d) Impurities / Stabilizing Additives
Sodium Citrate dihydrate	Sodium Citrate dihydrate	20.00 mg/ mL	6132-04-3	N/A
Propylene glycol	Propylene glycol	0.6 mL/ mL	57-55-6	N/A
Ethanol (96 %)	Ethanol (96 %)	0.052 mL/ mL	64-17-5	N/A
Water for Injection	Water for Injection	q.s. to 1 mL	7732-18-5	N/A

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(a) Chemical Name	(b) Common Name / Synonym	% Composition or other measure	(c) CAS No.	(d) Impurities / Stabilizing Additives
Nitrogen	Nitrogen	As required	7727-37-9	N/A

Section 4 – First Aid Measures

- Eye Exposure:** Rinse with water. Get medical attention if irritation develops and persists.
- Skin Exposure:** Rinse skin with water/shower. Get medical attention if irritation develops and persists.
- Ingestion:** Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately.
- Injection:** See patient package insert in shipping carton for complete information.
- Inhalation:** If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing.
Call a physician if symptoms develop or persist.
- Notes to physician:** Treat symptomatically. See patient package insert in shipping carton for complete information.

Section 5 – Fire-fighting Measures

- (a) **Extinguishing Media** Use fire-extinguishing media appropriate for surrounding materials. Water. Foam. Dry chemical or CO₂.
- (b) **Hazardous Combustion Products:** No unusual fire or explosion hazards noted.
- (c) **Special Protective Equipment / Precautions:** Wear suitable protective equipment.

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Section 6 – Accidental Release Measures

Spill: Wear protective clothing and equipment consistent with the degree of hazard. For all spills, isolate the spill area, restrict access, post the area for 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 labelled container for recovery or disposal. Water can be used for clean-up and decontamination operations.

Neutralize with caustic soda or soda ash.

Release to Air: Ensure adequate ventilation. Avoid inhalation of dust from the spilled material. Wear appropriate personal protective equipment.

Release to Water: N/A

Section 7 – Handling and Storage

General Handling: Isolation or enclosure is recommended to control exposure to this material


As a generality, when handling, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly. Use of a designated area is recommended for handling of potent materials. Wear personal protective equipment.

Storage Conditions: Store at 20° to 25°C (68° to 77° F) [see USP Controlled Room Temperature] and protect from light.

Section 8 - Exposure Controls / Personal Protection

(a) Exposure Limits

Compound	Issuer	Type	Exposure Limit
Melphalan HCl	OSHA	TLV	NE
	ACGIH	PEL	NE

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(b) Engineering Controls


Airborne exposure should be controlled primarily by engineering controls such as general dilution ventilation, local exhaust ventilation, or process enclosure. Local exhaust ventilation is generally preferred to general exhaust because it can control the contaminant at its source, preventing dispersion into the work area. An industrial hygiene survey involving air monitoring may be used to determine the effectiveness of engineering controls. Effectiveness of engineering controls intended for use with highly potent materials should be assessed by use of nontoxic surrogate materials. Avoid any open handling of this material, particularly for grinding, crushing, weighing, or other dust-generating or aerosol-generating procedures. Use a laboratory fume hood, vented enclosure, glovebox, or other effective containment.

Ventilation:

Local exhaust ventilation (LEV) is not appropriate at this level, since total containment should usually be used.

(c) Individual Protection Measures

Respiratory Protection:	Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).
Eye Protection:	Safety glasses with side shields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.
Skin Protection:	Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic nonlatex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy. To reduce the risk of contamination of skin and surfaces, wear two pairs of gloves. Remove the outer gloves after handling and cleanup of the material and remove the inner gloves only after removing other personal protective equipment.

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Other Protective Equipment:	For handling of laboratory scale quantities, a disposable lab coat or isolation gown over street clothes is recommended. Where significant quantities are handled, work clothing and booties may be necessary to prevent take-home contamination.
Additional Exposure Precautions:	None available

Section 9 - Physical and Chemical Properties

(a)	Appearance	White to off white lyophilized cake or powder
(b)	Odor	Not available
(c)	Odor Threshold	Not available
(d)	pH	Not available
(e)	Melting Point:	Not available
(f)	Initial Boiling Point:	Not available
(g)	Flash Point	Not available
(h)	Evaporation Rate:	Not available
(i)	Flammability	Not available
(j)	Upper Lower Flammability or Explosion	Not available
(k)	Vapor Pressure:	Not available
(l)	Vapor Density:	Not available
(m)	Relative Density	Not available
(n)	Solubility(ies)	Not available
(o)	Partition Coefficient: n-octanol/water	Not available
(p)	Auto-ignition Temperature	Not available
(q)	Decomposition Temperature	Not available
(r)	Viscosity	Not available

Section 10 - Stability and Reactivity

(a)	Reactivity	No data available.
(b)	Chemical Stability	The product is stable under normal conditions of use.

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(c)	Possibility of Hazardous Reactions	No dangerous reaction known under conditions of normal use.
(d)	Conditions to Avoid	None known.
(e)	Incompatible Materials	Strong oxidizing agents.
(f)	Hazardous Decomposition Products	Cl-. NOx. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

Section 11 - Toxicological Information

(a)	Likely Routes of Exposure	Ingestion, skin, eyes.
(b)	Symptoms related to the physical, chemical and toxicological characteristics	Nausea. Vomiting. Diarrhea. Fever. Chills. Difficulty swallowing. Cough. Painful or difficult urination. Blood in urine. Black or bloody stools. Bleeding or bruising. Pinpoint red spots on skin. Abdominal pain. Lower back or side pain.
(c)	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; cancer.

(d) Acute Toxicity


Component	Type	Route	Species	Dosage
Melphalan	LD ₅₀	Oral	Mouse	N/A
Sodium Chloride	LD ₅₀	Inhalation	Rat	N/A
Water	LD ₅₀	Oral	Rat	N/A

(e) Hazardous Chemical Listings

NTP: Listed

IARC: Listed

OSHA: Listed

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Section 12 - Ecological Information

(a) Ecotoxicity	No toxic effects recorded in aquatic microorganisms tested
(b) Persistence and degradability	This material contains an active pharmaceutical ingredient that has been shown to be chemically unstable in water. Hydrolysis may be a significant depletion mechanism
(c) Bioaccumulative potential	This material contains an active ingredient that will not have a tendency to bioaccumulate in the food chain.
(d) Mobility in soil	No data available
(e) Other Adverse Effects	No data available

Section 13 - Disposal Considerations

Waste Disposal: Dispose of any cleanup materials and waste residue according to all applicable laws and regulations.


Section 14 - Transport Information

DOT: Not regulated for transport.

(a) UN Number	None
(b) UN Proper Shipping Name	Consumer Commodity
(c) Transport Hazard Class(es)	Not Available
(d) Packing Group	Not Available
(e) Environmental Hazards	Not Available
(f) Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code)	Not Available
(g) Special Precautions	Classification and Labeling: See 173.4, 173.153 and 173.156

US Domestic Transport (DOT Requirements)

Proper shipping Name	Consumer Commodity
UN/NA number	None
Packing Group	Not applicable

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Classification Labeling
Limited Quantities

See 173.4, 173.153 and 173.156
May be able to ship as an Excepted or limited Quantity

IATA Classification and Labeling

(a)	UN Number	UN 3249
(b)	UN Proper Shipping Name	Consumer Commodity
(c)	Transport Hazard Class(es)	Class 6.1 Toxic
(d)	Packing Group	II
(e)	Environmental Hazards	Not Available
(f)	Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code)	Not Available
(g)	Special Precautions	Classification and Labeling: see 2.7 and 2.8

UN Classification and Labeling

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

Section 15 - Regulatory Information

Below is selected regulatory information chosen primarily for possible Athenex Pharmaceutical Division usage. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

U.S. Regulations:


TSCA: Exempt

CERCLA - N/A

SARA 302 - N/A

SARA 313 - N/A

Section 16 - Other Information

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As of the date of effectiveness, 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.

For additional information contact:

Athenex Pharmaceutical Division
10 N. Martingale Road, Suite 230
Schaumburg, IL 60173
847-886-9515

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

ACGIH	American Conference of Governmental Industrial Hygienists
AICS	Australian Inventory of Chemical Substances
AIHA	American Industrial Hygiene Association
ANSI	American National Standards Institute
CAS Number	Chemical Abstract Service Registry Number
CERCLA	Comprehensive Environmental Response Compensation and Liability Act (of
CHAN	Chemical Hazard Alert Notice
CHEMTREC	Chemical Transportation Emergency Center
DOT	Department of Transportation
DSL	Domestic Substances List
ECHA	European Chemicals Agency
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
EPA	Environmental Protection Agency
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
HEPA	High Efficiency Particulate Air (Filter)
HMIS	Hazardous Materials Identification System
IARC	International Agency for Research on Cancer
ICAO/IATA	International Civil Aviation Organization/International Air Transport
IMO	International Maritime Organization
KOW	Octanol/Water Partition Coefficient
LEL	Lower Explosive Limit
MSDS	Material Safety Data Sheet
MSHA	Mine Safety and Health Administration
NA	Not Applicable, except in Section 14 where NA = North America
NE	Not Established
NADA	New Animal Drug Application

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NAIF	No Applicable Information Found
NCI	National Cancer Institute
NDSL	Non-Domestic Substances List
NFPA	National Fire Protection Association
NIOSH	National Institute for Occupational Safety and Health
NPDES	National Pollutant Discharge Elimination System
NOS	Not Otherwise Specified
NTP	National Toxicology Program
OSHA	Occupational Safety and Health Administration
OEL	Occupational Exposure Limit
PEL	Permissible Exposure Limit (OSHA)
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
USP	United States Pharmacopeia
WEEL	Workplace Environmental Exposure Level (AIHA)
WHMIS	Workplace Hazardous Materials Information System

Signature Manifest

Document Number: SDS032

Revision: 02

Title: SDS032-Melphalan Hydrochloride for Injection

All dates and times are in Eastern Standard Time.

Melphalan SDS Revisions

Change Request

Name/Signature	Title	Date	Meaning/Reason
Emily Means (EMEANS)	QA Document Specialist		
Michael Scribner (MSCRIBNER)	Director of Corporate Quality		
Michael Spengler (MSPENGLER)	QC Applications Specialist		
Christopher Martensen (CMARTENSEN)	Quality Engineer-CSV	29 Aug 2019, 03:58:41 PM	Approved

Dept Approval

Name/Signature	Title	Date	Meaning/Reason
John Andre (JANDRE)	Regulatory Affairs Consultant	30 Aug 2019, 11:32:59 AM	Approved

Final QA Approval/Set Effective Date

Name/Signature	Title	Date	Meaning/Reason
Sheila Moran (SMORAN)	VP of Quality Assurance	30 Aug 2019, 12:11:58 PM	Approved