

 Pharmaceutical Division	Carmustine for Injection, USP		Safety Data Sheet (SDS)	
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Section 1 - Identification

- (a) **Product Identifier:** Carmustine for Injection, USP
- (b) **Product Code:** 70860-221
70860-222
70860-223
- Common/Trade Name:** Carmustine for Injection
- Chemical Name:** 1,3-bis(2-chloroethyl)-1-nitrosourea
- Chemical Family:** Nitrosourea
- (c) **Product Use:** Pharmaceutical, Injectable
- Product Type:** Regulated Prescription Drug
- Container Information:** 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:	Acute Toxicity – Oral – Category 2 Germ Cell Mutagenicity – Category 1B Carcinogenicity – Category 1B Toxic to Reproduction – Male Reproductive Toxicity – Category 1B Toxic To Reproduction – Developmental Toxicity (Repeated Exposure) - Category 1 Caution – Substance not yet fully tested.
(b)	Signal Word:	Danger
	Hazard Statement	H300: Fatal if swallowed. H350: May cause cancer. H360: May damage fertility or the unborn child.
	Symbols	

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	Precautionary Statement(s)	Do not breathe dust/fume/gas/mist/vapours/spray. Use personal protective equipment as required. Avoid contact during pregnancy/while nursing. Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Wash thoroughly after handling. Do not eat, drink or smoke when using this product.
(c)	Description of Hazards	Fatal if swallowed May cause genetic defects May cause cancer May damage fertility or the unborn child
(d)	Unknown Acute	N/A

Section 3 – Composition / Information on Ingredients

(a) Chemical Name	(b) Common Name / Synonym	% Composition or other measure	(c) CAS No.	(d) Impurities / Stabilizing Additives
1,3-bis(2-chloroethyl)-1-nitrosourea	Carmustine	100 mg per vial	154-93-8	N/A
Dehydrated Alcohol (for diluent)	Dehydrated Alcohol	2367.00 mg per vial	64-17-5	N/A

Section 4 – First Aid Measures

Eye Exposure:

Rinse immediately with plenty of water for at least 15 minutes. Keep eye wide open while rinsing. Obtain medical attention.

Skin Exposure:


Take off contaminated clothing and shoes immediately. Wash off immediately with plenty of water for at least 15 minutes. Discard contaminated clothing or wash before re-use. If exposed or concerned: Get medical attention/advice.

Ingestion:

IF SWALLOWED: Immediately call a POISON CENTRE or doctor/physician. Rinse mouth.

Injection:

See patient package insert in shipping carton for complete information.

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Inhalation: Move to fresh air. Oxygen or artificial respiration if needed. If exposed or concerned: Get medical attention/advice.


Notes to Physician: This product has been reported to interact with the following medications: cytotoxic and cytostatic medicines, Cimetidine, and certain vaccines. May cause harm to unborn child.

Section 5 – Fire-fighting Measures

- (a) **Extinguishing Media** Dry chemical, Water spray, Foam.
- (b) **Hazardous Decomposition Products:** Carbon oxides (CO_x), nitrogen oxides (NO_x), and, gaseous hydrogen chloride (HCl). Note* HCl gas can form flammable or explosive mixtures with alcohols or metals. In the event of fire and/or explosion do not breathe fumes.
- (c) **Special Protective Equipment / Precautions:** Use personal protective equipment. In the event of fire, wear self-contained breathing apparatus.

Section 6 - Accidental Release Measures

- Spill:** Clean spill area with a deactivating solution (if available) followed by detergent and water after spill pick-up. Handle waste materials, including gloves, protective clothing, contaminated spill cleanup material, etc., as appropriate for chemically and pharmacologically similar materials. Contain and collect spillage and place in container for disposal according to local regulations.
- Release to Air:** Avoid formation of dust and aerosols. Equipment such as a self-contained breathing apparatus may be needed.
- Release to Water:** Refer to local water authority. Drain disposal is not recommended. Refer to local, state, and federal disposal guidelines.

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Section 7 - Handling and Storage

General Handling: **Protective Measures:** Highly potent material. Avoid exposure - obtain special instructions before use. Avoid formation of dust and aerosols. Keep away from heat and sources of ignition. Prevent release to drains and waterways.
Hygiene: Wash hands and face before breaks and immediately after handling the product.

Storage Conditions: Store in the original primary packaging as provided. Store product and diluent in a refrigerator (2° to 8°C, 36° to 46°F).


Section 8 - Exposure Controls / Personal Protection

(a) **Exposure Limits:** None

(b) **Engineering Controls**


Ventilation: Use process enclosures, containment technology, or other engineering controls to keep airborne levels below recommended exposure limit. When handling quantities from 0-5 grams work in a designated laboratory or containment facility using a fume hood, biological safety cabinet (Class II, Type B1, or B2); glove box; and, approved vented enclosure. HEPA filtered exhaust with Bag-In/Bag-Out capacity referred for hoods, BSCs and glove boxes. Quantities exceeding 5 grams should be handled in a containment facility using appropriate containment isolation technology with isolator/glove box systems, glove bags, double/split butterfly valves, remote operations, direct process connections and systems, or automated systems. For manufacturing and pilot plant operations, the containment level should be to keep exposures as low as reasonably achievable.

Barrier/containment technology with isolator/glove bags, remote operations, direct process connections and systems, or automated systems should be used. Isolated work areas are required with rooms to provide thorough secondary containment.

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(c) Individual Protection Measures

<p>Respiratory Protection:</p>	<p>Use and selection of respiratory protection is based upon engineering controls in use and potential for aerosol generation. When engineering controls are not sufficient to control exposure, wear an approved respirator with NIOSH Class 100 or high efficiency particulate (HEPA) filters or cartridges when exposures are up to 10 times the exposure control guideline. Wear a loose-fitting (Tyvek or helmet type) HEPA powered-air purifying respirator (PAPR) when exposures are 10-25 times the exposure control guideline. Wear a full facepiece negative pressure respirator with Class 100 or HEPA filters when exposures are 25-50 times the exposure control guideline. Wear a tight-fitting, full facepiece HEPA PAPR when exposures are 50-100 times the exposure control guideline. Wear a hood shroud HEPA PAPR or full facepiece supplied air respirator operated in a pressure demand or other positive pressure mode when exposures are 100-1000 times the exposure control guideline.</p>
<p>Eye Protection:</p>	<p>Safety glasses with side-shields are recommended. Face shields or chemical safety goggles may be required if splash potential exists or if corrosive materials are present. Note: Choice of eye protection may be influenced by the type of respirator which is selected.</p>
<p>Hand Protection:</p>	<p>Wear double gloves. Wear gloves always when handling containers, including when unpacking, inspecting, or transporting within a facility. Disposable chemotherapy gloves made from nitrile, neoprene, polyurethane, and natural latex have been shown to have low permeability to many chemotherapy agents. Persons who are allergic to natural rubber latex should select gloves made from one of the other materials. Check gloves frequently to ensure that there are no small cuts or holes. Change gloves frequently, and remove immediately after overt contamination. Use care when removing and disposing of gloves to minimize exposure. If material is handled in solution, the solvent should also be considered when selecting protective clothing material.</p>
<p>Skin and Body Protection</p>	<p>For quantities up to 5 grams: wear disposable lab coat or coverall of low permeability; disposable wrist gauntlets/sleeves unless working in glove box. For quantities > 5 grams: wear full disposable coverall of low permeability; shoe covers; disposable wrist gauntlets/sleeves unless working in glove box. For manufacturing operations, gloves and booties should be taped to protective clothing to prevent gaps in PPE and air supplied full body suits may be required as associated with advanced respiratory protection</p>

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Other Protective Equipment:	Chemical-resistant gloves and impermeable body covering to minimize skin contact. If handled in a ventilated enclosure, as in a laboratory setting, respirator and goggles or face shield may not be required. Safety glasses are always required.
Additional Exposure Precautions:	In production settings, airline-supplied, hood-type respirators are preferred. Shower and change clothing if skin contact occurs.

Section 9 - Physical and Chemical Properties

(a) Appearance	Lyophilized pale yellow flakes or a congealed mass.
(b) Odor	Not available
(c) Odor Threshold	Not available
(d) pH	Not available
(e) Melting Point:	low melting point (30.5° to 32.0°C or 86.9° to 89.6°F)
(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 Limits	Not available
(k) Vapor Pressure:	Not available
(l) Vapor Density:	Not available
(m) Relative Density	Not available
(n) Solubility(ies)	Highly soluble in alcohol and lipids, and poorly soluble in water.
(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	Stable under recommended storage conditions
(b) Chemical Stability	Stable under recommended storage conditions. It is an alkylating agent. Decomposes to an oily

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		liquid at temperature of 35°C or warmer. Rapidly degrades in aqueous solutions at pH greater than 6.
(c)	Possibility of Hazardous Reactions	None known
(d)	Conditions to Avoid	Not established
(e)	Incompatible Materials	Polyvinylchloride
(f)	Hazardous Decomposition Products	Hazardous decomposition products formed under fire conditions.: carbon oxides (COx), nitrogen oxides (NOx), and gaseous hydrogen chloride (HCl).

Section 11 - Toxicological Information

(a)	Likely Routes of Exposure	Ingestion, Inhalation, Eye contact, Skin contact
(b)	Symptoms related to the physical, chemical and toxicological characteristics	Eye irritation: May be an eye irritant. Skin irritation: Mildly and or/transiently irritating to skin. Respiratory irritation: May be a respiratory irritant. Sensitization: Possible dermal sensitizer.
(c)	Delayed and immediate effects and also chronic effects from short- and long-term exposure	None available.

(d) Acute Toxicity

Component	Type	Route	Species	Dosage
Carmustine	LD ₅₀	Oral	Rat	20 mg/kg
		Oral	Mouse	19 mg/kg
		Intraperitoneal	Rat	17.42 mg/kg
		Intraperitoneal	Mouse	21.26 mg/kg
		Intravenous	Rat	13.8 mg/kg
		Intravenous	Mouse	45 mg/kg
		Intramuscular	Rat	79.6 mg/kg
		Intramuscular	Mouse	86.3 mg/kg
		Subcutaneous	Rat	83.2 mg/kg
		Subcutaneous	Mouse	24 mg/kg

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Genetic Toxicity

Mutagenicity Assessment: This material was positive in a battery of in vivo and in vitro genotoxicity assays.

Carcinogenicity

Carcinogenicity Assessment: This material was a carcinogen in animal studies. Some secondary cancers developed in persons with other cancers who were treated with this drug, either alone or in combination with other anticancer drugs. It is not known whether these were a result of the treatment with this drug, with one of the other drugs, or a result of progression of the underlying disease. This material is probably carcinogenic to humans.

Reproductive Toxicity

Assessment Reproductive Toxicity: Animal studies indicate that reproductive effects can occur. Compound may cause injury to male reproductive organs.

Developmental Toxicity

Developmental Toxicity Assessment: Substance was harmful to the fetus at doses that did not produce adverse effects in the maternal animal. Effects include: Potential embryo-fetal toxicity and teratogenicity.

(e) Hazardous Chemical Listings


NTP: Listed	IARC: 2A	OSHA: Listed	ACGIH: Not Listed
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Section 12 - Ecological Information

(a)	Ecotoxicity	Not available
(b)	Persistence and degradability	Not available
(c)	Bioaccumulative potential	The relatively low partition coefficient (log KOW = -1.3) indicates a low potential for bioaccumulation
(d)	Mobility in soil	Not available

Section 13 - Disposal Considerations

Waste Disposal: To avoid accidental exposure due to waste handling, place waste residue in a segregated, sealed plastic container. Used syringes, needles, and sharps should not be crushed, clipped, or recapped, but placed directly into an approved sharps container. Dispose of any cleanup materials and waste residue per all applicable laws and regulations, e.g., secure chemical landfill disposal.

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Section 14 - Transport Information

US DOT

UN/ID No. UN3249

Proper shipping name Medicine, solid, toxic, n.o.s. (Carmustine)

Class 6.1

Packing group II

Labelling 6.1

IMDG

UN/ID No. UN3249

Proper shipping name Medicine, solid, toxic, n.o.s. (Carmustine)

Class 6.1

Packing group II

Labelling 6.1

EmS 6.1-04

ICAO/IATA-DGR

UN/ID No. UN3249

Proper shipping name Medicine, solid, toxic, n.o.s. (Carmustine)

Class 6.1

Packaging group II

ADR/RID-Labels

Labelling 6.1

UN/ID No. UN3249

Proper shipping name Medicine, solid, toxic, n.o.s. (Carmustine)

Class 6.1

Packaging group II

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 – Not regulated


CERCLA - Not on this list

SARA 302 - Not on this list

SARA 313 - Not on this list

Section 16 - Other Information

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

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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
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

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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