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Section 1 - Identification

- (a) **Product Identifier:** Mesna Injection
- (b) **Product Code:** 70860-209
- Common/Trade Name:** Mesnex
- Chemical Name:** sodium-2-mercaptoethane sulfonate
- Chemical Family:** Detoxifying Agent
- (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) **GHS Classification of substance or mixture:**
- NFPA Rating**
 Health Hazard 2
 Fire Hazard 0
 Reactivity Hazard 0

(b) Signal Word, Hazard statement(s), Symbol(s), and/or Precautionary statement(s):

GHS Signal Word:	N/A
GHS Hazard Statement:	Mesna is a detoxifying agent used to prevent bleeding cystitis induced by chemotherapy from ifosamide. This product is low in toxicity. Minimal adverse health effect should occur from routine use of this product
GHS Symbols:	N/A
GHS Precautionary Statements:	N/A
Other Hazards	N/A

- (d) **Unknown Acute Toxicity** N/A

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Section 3 – Composition / Information on Ingredients


(a) Chemical Name	(b) Common Name / Synonym	% Composition or other measure	(c) CAS No.	(d) Impurities / Stabilizing Additives
sodium-2-mercaptoethane sulfonate	Mesna	100 mg/mL	19767-45-4	N/A
Disodium 2,2'-{1,2-ethanediylbis[(carboxymethyl)imino]} diacetate	Edetate Disodium	0.25 mg/mL	139-33-3	N/A
Phenylmethanol	Benzyl Alcohol	10.4 mg/mL	100-51-6	N/A
Sodium Hydroxide	Sodium Hydroxide	q.s. to adjust pH	1310-73-2	N/A
Nitrogen	Nitrogen	q.s.	7727-37-9	N/A
Water	Water for Injection	q.s to 10 mL	7732-18-5	N/A

q.s. – Quantity Sufficient

Section 4 – First Aid Measures

- Eye Exposure:** Immediately flush eyes with water for at least 15 minutes. Seek medical attention.
- Skin Exposure:** Remove contaminated clothing immediately. Flush area with water for at least 15 minutes. Wash exposed area with soap and water. Seek medical attention.
- Ingestion:** Do not induce vomiting. Flush mouth out with water immediately. Seek medical attention.
- Injection:** Local redness and pain are the primary symptoms of accidental injection in an occupational setting. Medical personnel are not anticipated to experience over-exposures to the therapeutic doses of this product. However, effects including headache, fatigue, nausea, vomiting, diarrhea, limb pain, hypotension and allergy may occur. See package insert for other adverse reactions associated with therapeutic doses of this product.
- Inhalation:** Move exposed subject to fresh air immediately. Give artificial respiration and cardiopulmonary resuscitation (CPR) if required. Seek medical attention.

Notes to Physician: See patient package insert in shipping carton for complete information

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Section 5 – Fire-fighting Measures

- (a) **Extinguishing Media** Use water spray, foam or ABC multi-purpose extinguisher as appropriate for surrounding fire and materials.
- (b) **Hazardous Combustion Products:** When heated to decomposition, it emits toxic fumes. Smoke and toxic fumes of Cl.
- (c) **Special Protective Equipment / Precautions:** Evacuate personnel. Wear self-containing breathing apparatus and protective clothing.

Section 6 - Accidental Release Measures

- Spill:** Use absorbent towels or brooms to clean up spill. Wipe surface area clean with soap and water.
- Release to Air:** If aerosolized, reduce exposures by ventilating area; clean up spill immediately to prevent evaporation.
- Release to Water:** Refer to local water authority. Drain disposal is not recommended; refer to local, state, and federal disposal guidelines.


Section 7 - Handling and Storage

- General Handling:** When handling pharmaceutical products, avoid all contact and inhalation of dust, fumes, mist, and/or vapors associated with the product.
- Storage Conditions:** Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature.]

Section 8 - Exposure Controls / Personal Protection

(a) Exposure Limits

Compound	Issuer	Type	Exposure Limit
Mesna	OSHA ACGIH	PEL	NE
		TWA	NE
		STEL	NE
Edetate Disodium	OSHA ACGIH	PEL	NE
		TWA	NE
		STEL	NE
Benzyl Alcohol	OSHA ACGIH	PEL	NE
		TWA	NE
		STEL	NE

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(b) Engineering Controls


Ventilation: General room ventilation is satisfactory. Use local exhaust ventilation if necessary.

(c) Individual Protection Measures

Respiratory Protection:	With satisfactory ventilation, respiratory protection is usually not required.
Eye Protection:	Safety glasses or goggles recommended
Skin Protection:	Disposable garments if direct skin contact is anticipated.
Other Protective Equipment:	Not established
Additional Exposure Precautions:	Not established.

Section 9 - Physical and Chemical Properties

(a) Appearance	clear, colorless, aqueous solution
(b) Odor	Not available
(c) Odor Threshold	Not available
(d) pH	7.5-8.5
(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 Limits	Not available
(k) Vapor Pressure:	Not available
(l) Vapor Density:	Not available
(m) Relative Density	Not available
(n) Solubility(ies)	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


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Section 10 - Stability and Reactivity

(a)	Reactivity	Not determined
(b)	Chemical Stability	Stable under standard use and storage conditions.
(c)	Possibility of Hazardous Reactions	Hazardous polymerization will not occur
(d)	Conditions to Avoid	No conditions contributing to instability are known to exist
(e)	Incompatible Materials	Keep away from strong oxidizers and cisplatin
(f)	Hazardous Decomposition Products	Heat may cause product to decompose, destroying the product or producing toxic fumes.

Section 11 - Toxicological Information

(a)	Likely Routes of Exposure	Inhalation, eye/skin contact or ingestion
(b)	Symptoms related to the physical, chemical and toxicological characteristics	None known from occupational exposure. In clinical use, adverse effects have included hypotension, hypertension, nausea, bradycardia, fever, vomiting, hypoxia, tachycardia and anemia.
(c)	Delayed and immediate effects and chronic effects from short and long term exposure	The primary health effects anticipated in an occupational setting include irritation of eyes and skin as well as redness and local swelling after accidental injection. In case of overexposure by injection, effects such as headache, fatigue, vomiting, nausea, diarrhea, limb pain, hypotension and allergy may occur. Potential adverse reactions from prescribed doses and overdoses are described in the package insert. Adverse reactions from therapeutic dose include: headache, fatigue, nausea, diarrhea, limb pain, hypotension, and vomiting. Allergic reaction may also occur. Occupational exposure has not been fully investigated

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(d) Acute Toxicity

Component	Type	Route	Species	Dosage
Mesna	LD ₅₀	Oral	Rat	4440 mg/kg
	LD ₅₀	Oral	Mouse	6102 mg/kg
	LD ₅₀	Intravenous	Rat	1510 mg/kg
	LD ₅₀	Intravenous	Mouse	1720 mg/kg
	LD ₅₀	Intraperitoneal	Rat	1251 mg/kg
	LD ₅₀	Intraperitoneal	Mouse	2005 mg/kg
	LD ₅₀	Intramuscular	Rat	2313 mg/kg
	LD ₅₀	Intramuscular	Mouse	1200 mg/kg

Pregnancy Category B: Mesna Injection should be given to a pregnancy woman only if the benefits clearly outweigh any possible risk.

(e) Hazardous Chemical Listings

NTP: Not Listed **IARC:** Not Listed **OSHA:** Not Listed

Section 12 - Ecological Information

(a)	Ecotoxicity	Not determined for product
(b)	Persistence and degradability	Not determined for product
(c)	Bioaccumulative potential	Not determined for product
(d)	Mobility in soil	Not determined for product
(e)	Other Adverse Effects	Not determined for product


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 as a dangerous good.
IATA: Not regulated as a dangerous good.
IMDG: Not regulated as a dangerous good.

(a)	UN Number	N/A
(b)	UN Proper Shipping Name	N/A
(c)	Transport Hazard Class(es)	N/A
(d)	Packing Group	N/A
(e)	Environmental Hazards	N/A

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(f)	Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code)	N/A
(g)	Special Precautions	N/A

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 311/312: Not on this list
- SARA 313 - Not on this list
- OSHA – 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 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 1980

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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
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: SDS022

Revision: 01

Title: Mesna Injection SDS

All dates and times are in Eastern Standard Time.

Mesna Inj SDS

Change Request

Name/Signature	Title	Date	Meaning/Reason
Christopher Martensen (CMARTENSEN)	Quality Engineer-CSV		
Michael Scribner (MSCRIBNER)	Director of Quality	30 Jan 2018, 05:18:31 PM	Approved

Dept Approval

Name/Signature	Title	Date	Meaning/Reason
John Andre (JANDRE)	Regulatory Affairs Consultant	07 Feb 2018, 08:20:44 AM	Approved

Final QA Approval/Set Effective Date

Name/Signature	Title	Date	Meaning/Reason
Sheila Moran (SMORAN)	VP of Quality Assurance	07 Feb 2018, 12:31:30 PM	Approved