

	Sagent Pharmaceuticals, Inc.				
	Mesna Injection			Safety Data Sheet (SDS)	
	SDS Issue Date: Apr. 24, 2015	SDS No.: SDS 037	SDS Version No.: 2.0	Form No.: R-SOP-009-F001	Page: 1 of 9

Section 1 - Identification

- (a) **Product Identifier:** Mesna Injection
- (b) **Product Code:** 25021-201
- Common/Trade Name:** Mesnex®
- Chemical Name:** sodium-2-mercaptoethane sulfonate
- Chemical Family:** Detoxifying Agent
- (c) **Product Use:** Pharmaceutical
- Product Type:** Regulated Prescription Drug
- Container Information:** Vials
- (d) **Distributor:** Sagent Pharmaceuticals, Inc., 1901 N. Roselle Rd, Suite 700, Schaumburg, IL 60195, 847-908-1600
- (e) **Emergency Telephone:** 866-625-1618

Section 2 - Hazards Identification

- (a) **Classification:**

NFPA Rating

Health Hazard	2
Fire Hazard	0
Reactivity Hazard	0

(b) Signal Word, Hazard statement(s), Symbol(s), and/or Precautionary statement(s):	(c) Description of Hazards:
<u>Signal Word:</u>	- Not Available
<u>Hazard Statements</u> - 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	

- (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	11.44 mg/mL	100-51-6	N/A
Sodium Hydroxide	Sodium Hydroxide	q.s to pH	1310-73-2	N/A
Nitrogen	Nitrogen	q.s.	7727-37-9	N/A
Water	Water for Injection	q.s. to 1 mL	7732-18-5	N/A

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.

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

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:** Stored at 20° - 25°C (68° - 77°F). Excursions permitted between 15°C and 30°C (between 59°F and 86°F). [See USP Controlled Room Temperature]. Follow instructions provided in packaging.

Section 8 - Exposure Controls / Personal Protection

(a) Exposure Limits

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

(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, sterile, aqueous solution
(b)	Odor	Not available
(c)	Odor Threshold	Not available
(d)	pH	6.5-8.5
(e)	Melting Point:	275°C
(f)	Initial Boiling Point:	~100°C (212°F)
(g)	Flash Point	Not available
(h)	Evaporation Rate:	>1 (n-BuAc = 1)

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(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	Specific Gravity ~1
(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

Section 10 - Stability and Reactivity

(a)	Reactivity	Not Available
(b)	Chemical Stability	Stable
(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	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 over-exposure by injection, effects such as headache, fatigue, vomiting, nausea, diarrhea, limb pain, hypotension and allergy may occur.

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(c)	Delayed and immediate effects and also chronic effects from short and long term exposure	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
Mesna	LD ₅₀	Oral	Mouse	6102 mg/kg
Mesna	LD ₅₀	Intravenous	Rat	1510 mg/kg
Mesna	LD ₅₀	Intravenous	Mouse	1720 mg/kg
Mesna	LD ₅₀	Intraperitoneal	Rat	1251 mg/kg
Mesna	LD ₅₀	Intraperitoneal	Mouse	2005 mg/kg
Mesna	LD ₅₀	Intramuscular	Rat	2313 mg/kg
Mesna	LD ₅₀	Intramuscular	Mouse	1200 mg/kg

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

(e) Hazardous Chemical Listings

NTP: Not Listed

IARC: Not Listed

OSHA: Not Listed

Section 12 - Ecological Information

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

Section 13 - Disposal Considerations

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

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Section 14 - Transport Information

(a)	UN Number	Not available
(b)	UN Proper Shipping Name	Not available
(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	Not available

DOT: Not Regulated

ICAO/IATA: Not Regulated

IMO: Not Regulated

Section 15 - Regulatory Information

Below is selected regulatory information chosen primarily for possible Sagent 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 - No

CERCLA - Not on this list

SARA 302 - Not on this list

SARA 313 - Not on this list

OSHA Substance Specific - No

California Proposition 65 – Not Listed

Section 16 - Other Information

As of the date of issuance, 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

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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:

Sagent Pharmaceuticals, Inc.
1901 N. Roselle Rd, Suite 700
Schaumburg, IL 60195
847-908-1600

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)
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 Association
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

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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