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Section 1 - Identification


- (a) **Product Identifier:** Busulfan Injection
- (b) **Product Code:** 70860-216
- Common/Trade Name:** Busulfex Injection
- Chemical Name:** 1,4-butanediol dimethanesulfonate
- Chemical Family:** Alkylating 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:** Acute Toxicity, Oral (Category 3)
 Germ cell mutagenicity (Category 2)
 Carcinogenicity (Category 1A)
 Reproductive toxicity (Category 2)

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

GHS Signal Word:	Toxic
GHS Hazard Statement:	H301 Toxic if swallowed. H360FD Possible risk of impaired fertility. H360FD Possible risk of harm to the unborn child. H340 May cause heritable genetic damage H341 Suspected of causing genetic defects. H350 May causes cancer. H361 Suspected of damaging fertility or the unborn child H370 Very toxic: danger of very serious irreversible effects through inhalation, in contact with skin and if swallowed.


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GHS Symbols:	
GHS Precautionary Statements:	<p>P264 Wash your hands thoroughly after handling.</p> <p>P270 Do not eat or smoke when using this product.</p> <p>P201 Obtain special instructions before use</p> <p>P202 Do not handle until all safety precautions have been read and understood.</p> <p>P281 Use personal protective equipment as required.</p> <p>P301+P310 IF SWALLOWED: Call a POISON CENTER or Doctor / physician if you feel unwell.</p> <p>P321 Specific treatment(see...on this label)</p> <p>P330 IF SWALLOWED: rinse mouth.</p> <p>P308+P313 IF exposed or concerned: Get medical advice / attention.</p> <p>P405 Store locked up.</p> <p>P501 Dispose of contents/container in accordance with Local / regional / national / international regulations.</p>
Other Hazards	N/A

(d) **Unknown Acute Toxicity** 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
1,4-butanediol dimethanesulfonate	Busulfan	6.00 mg/mL	55-98-1	N/A
N, N-dimethylacetamide, EP	DMA, Dimethylacetamide	308.90 mg/mL	127-19-5	N/A
Polyethylene Glycol, NF (PEG 400) [Super Refined PEG 400-LQ-(MH)]	Polyethylene Glycol	752.10 mg/mL	25332-68-3	N/A


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Section 4 – First Aid Measures

- Eye Exposure:** Immediately flush eyes thoroughly with water for at least 15 minutes. Notify medical personnel and supervisor.
- Skin Exposure:** Immediately wash affected area thoroughly with soap and water for at least 15 minutes. If irritation occurs, notify medical personnel and supervisor.
- Ingestion:** Immediately drink 2-3 glasses of water. Notify medical personnel and supervisor.
- Injection:** Not available
- Inhalation:** Immediately move to fresh air and notify medical personnel and supervisor.
- Notes to Physician:** Treat symptomatically and supportively. See patient package insert in shipping carton for complete information.

Section 5 – Fire-fighting Measures

- (a) **Extinguishing Media** Water mist, carbon dioxide, powder, foam.
- (b) **Hazardous Combustion Products:** Special exposure hazards arising from combustion products include CO_x, NO_x, SO_x
- (c) **Special Protective Equipment / Precautions:** Protective clothing and a self-contained breathing apparatus is suggested.
- Use water spray to cool the fire exposed containers as well as for protection of people.

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Section 6 - Accidental Release Measures

- Spill:** Wear personal protective equipment (goggles and gloves). Absorb to cloth or sand promptly and deposit in suitable containers for disposal.
- Remove to permitted waste disposal. Follow local regulations for chemical waste.
- Prevent spillage from directly entering ground or navigable waters.
- Release to Air:** Not available.
- Release to Water:** Not available. Refer to the local water authority; drain disposal is not recommended. Refer to local, state and federal guidelines.

Section 7 - Handling and Storage

- General Handling:** Use local exhaust ventilation. Use personal protective equipment (protective clothes, goggles and latex gloves).
- Storage Conditions:** Store unopened vials of Busulfan refrigerated between 2° and 8°C (36° and 46°F).


Section 8 - Exposure Controls / Personal Protection

(a) Exposure Limits

Compound	Issuer	Type	Exposure Limit
Busulfan	OSHA	PEL	NA
	ACGIH	TLV	NA
N,N-dimethylacetamide (DMA)	OSHA	PEL-TWA	10 ppm (skin)
	ACGIH	TLV-TWA	10 ppm (skin)
Polyethylene Glycol 400 (PEG-400)	OSHA	PEL	NA
	ACGIH	TLV	NA

Notes:

OSHA PEL: US Occupational Safety and Health Administration – Permissible Exposure Limit
 ACGIH TLV: American Conference of Governmental Industrial Hygienists – Threshold Limit Value.

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(b) Engineering Controls


Ventilation: Substance should only be handled in well ventilated areas.

(c) Individual Protection Measures

Respiratory Protection:	A half-face organic vapor respirator is suggested if ventilation is insufficient.
Eye Protection:	Safety goggles
Skin Protection:	Protective clothing (i.e. lab coat)
Other Protective Equipment:	N/A
Additional Exposure Precautions:	Wash hands following use. No eating, drinking, or smoking while handling this product.

Section 9 - Physical and Chemical Properties

(a) Appearance	Clear, colorless, sterile, solution
(b) Odor	Not available
(c) Odor Threshold	Not available
(d) pH	3.4 to 3.9
(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)	Yes, in water is 0.1 g per L
(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	Not determined
(d)	Conditions to Avoid	High Temperatures
(e)	Incompatible Materials	Strong oxidizers, strong acids and halogenated compounds in the presence of iron.
(f)	Hazardous Decomposition Products	Carbon oxides (CO _x), nitrogen oxides (NO _x), and sulphur oxides(SO _x).

Section 11 - Toxicological Information

(a)	Likely Routes of Exposure	Skin, inhalation, accidental ingestion
(b)	Symptoms related to the physical, chemical and toxicological characteristics	Potential adverse side effects include effects on hematological system (anemia and decreased platelets), symptoms of increased risk of bleeding and tiredness. See package insert for details.
(c)	Delayed and immediate effects and chronic effects from short and long term exposure	Acute effects include anemia, hair loss, inflammation of stomach lining, nausea and vomiting. The nervous system has also been reported as affected by means of insomnia, anxiety and dizziness, and shortness of breath has also occurred. This product's active ingredient, Busulfan, is considered a potential reproductive toxicant, possible teratogen, developmental toxicant, a mutagen, and a carcinogen. See package insert for details.

(d) Acute Toxicity

Component	Type	Route	Species	Dosage
Busulfan	LD ₅₀	Oral	Mouse	110mg/kg

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DMA	LD ₅₀	Oral	Mouse	5000mg/kg
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(e) Hazardous Chemical Listings

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

Section 12 - Ecological Information


(a) Ecotoxicity	No applicable ecological information found.
(b) Persistence and degradability	No applicable ecological information found.
(c) Bioaccumulative potential	No applicable ecological information found.
(d) Mobility in soil	No applicable ecological information found.
(e) Other Adverse Effects	No applicable ecological information found.

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

(a) UN Number	2810
(b) UN Proper Shipping Name	N/A
(c) Transport Hazard Class(es)	Toxic liquid, organic, n.o.s.
(d) Packing Group	N/A
(e) Environmental Hazards	N/A
(f) Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code)	N/A
(g) Special Precautions	N/A

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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: California Proposition 65: Busulfan is listed as a carcinogen and a developmental toxicant.

TSCA – Not regulated

CERCLA - Not listed

SARA 302 - Not available

SARA 311/312: The product meets the following definitions under these regulations: An immediate health hazard, a delayed/chronic health hazard.

SARA 313 - Not available

OSHA – Not available

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
CHAN	Chemical Hazard Alert Notice
CHEMTREC	Chemical Transportation Emergency Center
DOT	Department of Transportation

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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: SDS030

Revision: 02

Title: Busulfan Injection

All dates and times are in Eastern Standard Time.

Busulfan SDS Revision

Change Request

Name/Signature	Title	Date	Meaning/Reason
Michael Scribner (MSCRIBNER)	Director of Corporate Quality		
Michael Spengler (MSPENGLER)	QC Applications Specialist		
Christopher Martensen (CMARTENSEN)	Quality Engineer-CSV		
Emily Means (EMEANS)	QA Document Specialist	18 Mar 2019, 08:17:03 AM	Approved

Dept Approval

Name/Signature	Title	Date	Meaning/Reason
John Andre (JANDRE)	Regulatory Affairs Consultant	19 Mar 2019, 02:03:39 PM	Approved

Final QA Approval/Set Effective Date

Name/Signature	Title	Date	Meaning/Reason
Sheila Moran (SMORAN)	VP of Quality Assurance	19 Mar 2019, 02:20:49 PM	Approved