 <b>Pharmaceutical Division</b>	<b>Doxorubicin Hydrochloride Injection</b>		<b>Safety Data Sheet (SDS)</b>	
	Effective Date: <b>11OCT2017</b>	SDS No.: <b>SDS020</b>	Revision No: <b>01</b>	Page <b>1 of 9</b>

### Section 1 - Identification

- (a) **Product Identifier:** Doxorubicin Hydrochloride Injection
- (b) **Product Code:** 70860-208
- Common/Trade Name:** Doxorubicin, Adriamycin, Adriablastina; Adriblastin; Adriblastina; Adiblastine
- Chemical Name:** 5,12-Naphthacenedione,10-[(3-amino-2,3,6-trideoxy- $\alpha$ -L-lyxo-hexopyranosyl)oxy]-7,8,9,10-tetrahydro-6,8,11-trihydroxy-8-(hydroxylacetyl)-1-methoxy-,hydrochloride(8S-cis)-
- Chemical Family:** Cytotoxic, anthracycline, topoisomerase II inhibitor
- (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:** Germ Cell Mutagenicity: Category 1B  
Reproductive Toxicity: Category 1B  
Carcinogenicity: Category 1B

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


**GHS Signal Word:** DANGER

**GHS Hazard Statement:**

- H340 - May cause genetic defects
- H350 - May cause cancer
- H360FD - May damage fertility. May damage the unborn child.

**GHS Symbols:**



 <b>Pharmaceutical Division</b>	<b>Doxorubicin Hydrochloride Injection</b>		<b>Safety Data Sheet (SDS)</b>	
	Effective Date: <b>11OCT2017</b>	SDS No.: <b>SDS020</b>	Revision No: <b>01</b>	Page <b>2 of 9</b>

<b>GHS Precautionary Statements:</b>	<ul style="list-style-type: none"> <li>▪ P201 - Obtain special instructions before use</li> <li>▪ P202 - Do not handle until all safety precautions have been read and understood</li> <li>▪ P281 - Use personal protective equipment as required</li> <li>▪ P308 + P313 - IF exposed or concerned: Get medical attention/advice</li> <li>▪ P405 - Store locked up</li> <li>▪ P501 - Dispose of contents/container in accordance with all local and national regulations.</li> </ul>
<b>Other Hazards</b>	<ul style="list-style-type: none"> <li>▪ No data available</li> </ul>


(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
5,12-Naphthacenedione,10-[(3-amino-2,3,6-trideoxy- $\alpha$ -L-lyxo-hexopyranosyl)oxy]-7,8,9,10-tetrahydro-6,8,11-trihydroxy-8-(hydroxyacetyl)-1-methoxy-,hydrochloride(8S-cis)-	Doxorubicin Hydrochloride	2 mg/mL	25316-40-9	N/A
Sodium Chloride	Sodium Chloride	9 mg/mL	647-14-15	N/A
Hydrochloric Acid	Hydrochloric Acid	q.s to pH adjustment	7647-01-0	N/A
Water for Injection	Water for Injection	q.s to 1 mL	7732-18-5	N/A
Nitrogen NF	Nitrogen	*	7727-37-9	N/A

\*Nitrogen is used during compounding and to transfer the product through filtration train during filtration and filling.

q.s. = quantity sufficient

 <b>Pharmaceutical Division</b>	<b>Doxorubicin Hydrochloride Injection</b>		<b>Safety Data Sheet (SDS)</b>	
	Effective Date: <b>11OCT2017</b>	SDS No.: <b>SDS020</b>	Revision No: <b>01</b>	Page <b>3 of 9</b>

#### Section 4 – First Aid Measures

- Eye Exposure:** Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
- Skin Exposure:** Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
- Ingestion:** Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.
- Injection:** In cases of accidental injection, wash and disinfect area, seek emergency medical attention.
- Inhalation:** Remove to fresh air and keep patient at rest. Seek medical attention immediately.
- Notes to Physician:** None


#### Section 5 – Fire-fighting Measures

- (a) **Extinguishing Media** Extinguish fires with CO<sub>2</sub>, extinguishing powder, foam, or water.
- (b) **Hazardous Combustion Products:** Formation of toxic gases is possible during heating or fire. Fine particles (such as dust and mists) may fuel fires/explosions.
- (c) **Special Protective Equipment / Precautions:** During all fire-fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

#### Section 6 - Accidental Release Measures

**Spill:** Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly. Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel. Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

**Release to Air:** Should be avoided.

 <b>Pharmaceutical Division</b>	<b>Doxorubicin Hydrochloride Injection</b>		<b>Safety Data Sheet (SDS)</b>	
	Effective Date: <b>11OCT2017</b>	SDS No.: <b>SDS020</b>	Revision No: <b>01</b>	Page <b>4 of 9</b>

**Release to Water:** Should be avoided. Refer to local, state and federal guidelines.

**Section 7 - Handling and Storage**

**General Handling:** Restrict access to work area. Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). It is recommended that all operations be fully enclosed and no air recirculated. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

**Storage Conditions:** Store all vials at 2° to 8°C (36° to 46°F). Protect from light.

**Section 8 - Exposure Controls / Personal Protection**

**(a) Exposure Limits**

Refer to available public information for specific member state Occupational Exposure Limits.


Compound	Issuer	Type	Exposure Limit
Doxorubicin Hydrochloride	OSHA	PEL	NE
	ACGIH	TWA	NE

**(b) Engineering Controls**

Handle in a well-ventilated area. General room ventilation is adequate unless the process generates dust, mist or fumes.

**(c) Individual Protection Measures**

Respiratory Protection:	Use respiratory protection unless adequate local exhaust ventilation is provided or exposure assessment demonstrates that exposures are within recommended exposure guidelines.
Eye Protection:	Wear safety glasses or goggles if eye contact is possible.
Skin Protection:	Impervious disposable protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

 <b>Pharmaceutical Division</b>	<b>Doxorubicin Hydrochloride Injection</b>		<b>Safety Data Sheet (SDS)</b>	
	Effective Date: <b>11OCT2017</b>	SDS No.: <b>SDS020</b>	Revision No: <b>01</b>	Page <b>5 of 9</b>


Other Protective Equipment:	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
Additional Exposure Precautions:	None

### Section 9 - Physical and Chemical Properties

<b>(a) Appearance</b>	Clear, red, aqueous solution
<b>(b) Odor</b>	No odor
<b>(c) Odor Threshold</b>	Not available
<b>(d) pH</b>	2.5-4.5
<b>(e) Melting Point:</b>	Not available
<b>(f) Initial Boiling Point:</b>	100-105°C
<b>(g) Flash Point</b>	Not available
<b>(h) Evaporation Rate:</b>	Not available
<b>(i) Flammability</b>	Not available
<b>(j) Upper Lower Flammability or Explosion Limits</b>	Not available
<b>(k) Vapor Pressure:</b>	Not available
<b>(l) Vapor Density:</b>	Not available
<b>(m) Relative Density</b>	Not available
<b>(n) Solubility(ies)</b>	Soluble in water
<b>(o) Partition Coefficient: n-octanol/water</b>	Not available
<b>(p) Auto-ignition Temperature</b>	Not available
<b>(q) Decomposition Temperature</b>	Not available
<b>(r) Viscosity</b>	Not available

### Section 10 - Stability and Reactivity

<b>(a) Reactivity</b>	No data available
<b>(b) Chemical Stability</b>	Stable at normal temperature and pressures.
<b>(c) Possibility of Hazardous Reactions</b>	No data available

 <b>Pharmaceutical Division</b>	<b>Doxorubicin Hydrochloride Injection</b>		<b>Safety Data Sheet (SDS)</b>	
	Effective Date: <b>11OCT2017</b>	SDS No.: <b>SDS020</b>	Revision No: <b>01</b>	Page <b>6 of 9</b>

<b>(d) Conditions to Avoid</b>	Fine particles (such as dust and mists) may fuel fires/explosions.
<b>(e) Incompatible Materials</b>	As a precautionary measure, keep away from strong oxidizers
<b>(f) Hazardous Decomposition Products</b>	No hazardous decomposition products are known.

### Section 11 - Toxicological Information

<b>(a) Likely Routes of Exposure</b>	Inhalation, ingestion, skin contact or eye contact.
<b>(b) Symptoms related to the physical, chemical and toxicological characteristics</b>	Bone marrow suppression is the most serious adverse effect seen during clinical use. Drugs of this class have been associated with rare, but potentially serious cardiac events. These events have not been observed from occupational exposures, however, those with preexisting cardiovascular illnesses may be at increased risk from exposure.
<b>(c) Delayed and immediate effects and chronic effects from short and long-term exposure</b>	<p>Short-term: May cause eye and skin irritation (based on components).</p> <p>Long-term: Repeat-dose studies in animals have shown a potential to cause adverse effects on testes, the developing fetus.</p>

#### (d) Acute Toxicity


Based on available data, the classification criteria are not met.

Component	Type	Route	Species	Dosage
Doxorubicin Hydrochloride	LD <sub>50</sub>	Oral	Mouse	698 mg/kg
	LD <sub>50</sub>	Para-periosteal	Mouse	1.2 mg/kg
	LD <sub>50</sub>	Intravenous	Rat	12.5 mg/kg
	LD <sub>50</sub>	Intraperitoneal	Rat	16 mg/kg

#### (e) Hazardous Chemical Listings

**NTP:** Group 2: Reasonably Anticipated to Be A Human Carcinogen  
**IARC:** Not listed  
**OSHA:** Not listed  
**ACGIH:** Not Listed

### Section 12 - Ecological Information

 <b>Pharmaceutical Division</b>	<b>Doxorubicin Hydrochloride Injection</b>		<b>Safety Data Sheet (SDS)</b>	
	Effective Date: <b>11OCT2017</b>	SDS No.: <b>SDS020</b>	Revision No: <b>01</b>	Page <b>7 of 9</b>

<b>(a) Ecotoxicity</b>	Avoid release into the environment. Runoff from fire control or dilution water may cause pollution.
<b>(b) Persistence and degradability</b>	Not Available.
<b>(c) Bioaccumulative potential</b>	Not Available
<b>(d) Mobility in soil</b>	Not available
<b>(e) Other Adverse Effects</b>	Not 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 as a dangerous good.  
**IATA:** Not regulated as a dangerous good.  
**IMDG:** Not regulated as a dangerous good.


<b>(a) UN Number</b>	N/A
<b>(b) UN Proper Shipping Name</b>	N/A
<b>(c) Transport Hazard Class(es)</b>	N/A
<b>(d) Packing Group</b>	N/A
<b>(e) Environmental Hazards</b>	N/A
<b>(f) Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code)</b>	N/A
<b>(g) Special Precautions</b>	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

 <b>Pharmaceutical Division</b>	<b>Doxorubicin Hydrochloride Injection</b>		<b>Safety Data Sheet (SDS)</b>	
	Effective Date: <b>11OCT2017</b>	SDS No.: <b>SDS020</b>	Revision No: <b>01</b>	Page <b>8 of 9</b>

### 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
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



 <b>Pharmaceutical Division</b>	<b>Doxorubicin Hydrochloride Injection</b>		<b>Safety Data Sheet (SDS)</b>	
	Effective Date: <b>11OCT2017</b>	SDS No.: <b>SDS020</b>	Revision No: <b>01</b>	Page <b>9 of 9</b>

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:** SDS020

**Revision:** 01

**Title:** Doxorubicin Hydrochloride Injection

All dates and times are in Eastern Standard Time.

**SDS020**

### Change Request

Name/Signature	Title	Date	Meaning/Reason
Christopher Martensen (CMARTENSEN)	Quality Engineer-CSV		
Michael Scribner (MSCRIBNER)	Director of Quality	03 Oct 2017, 04:58:14 PM	Approved

### Dept Approval

Name/Signature	Title	Date	Meaning/Reason
John Andre (JANDRE)	Regulatory Affairs Consultant	06 Oct 2017, 02:26:40 PM	Approved

### Final QA Approval/Set Effective Date

Name/Signature	Title	Date	Meaning/Reason
Sheila Moran (SMORAN)	VP of Quality Assurance	06 Oct 2017, 02:54:02 PM	Approved