
 <b>Athenex</b> Pharmaceutical Division	<b>Decitabine for Injection</b>		<b>Safety Data Sheet (SDS)</b>	
	Effective Date: <b>20AUG2021</b>	SDS No.: 046	Revision No: <b>1.0</b>	<b>Page 1 of 10</b>


### Section 1 - Identification

- (a) **Product Identifier:** Decitabine for Injection
- (b) **NDC:** 70860-219
- Common/Trade Name:** Dacogen<sup>®</sup>
- Chemical Name:** 4-amino-1-(2-deoxy- $\beta$ -D-erythropentofuranosyl)-1,3,5-triazin-2(1H)-one
- Chemical Family:** Nucleoside Metabolic Inhibitor
- (c) **Product Use:** Reduces the growth of cancer cells. Used to treat adults with myelodysplastic syndromes.
- 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:** US OSHA:  
 H302 Acute toxicity, Oral (Category 4)  
 H315 Skin irritation (Category 2)  
 H319 Eye irritation (Category 2A)  
 H341 Germ cell mutagenicity (Category 2)  
 H360 Reproductive toxicity (Category 1B)  
 H335 Specific target organ toxicity - single exposure (Category 3), Respiratory system

<b>(b) Signal Word, Hazard statement(s), Symbol(s), and/or Precautionary statement(s):</b>	<b>(c) Description of Hazards:</b>
	Signal Word: Danger

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(b) Signal Word, Hazard statement(s), Symbol(s), and/or Precautionary statement(s):	(c) Description of Hazards:
<u>Hazard Statements:</u> H302 H315 H319 H335 H341 H360	Harmful if swallowed. Causes skin irritation. Causes serious eye irritation. May cause respiratory irritation. Suspected of causing genetic defects. May damage fertility or the unborn child.
<u>Precautionary Statements:</u> P202 P261 P264 P270 P271 P280 P301 + P312 P302 + P352 P304 + P340 P305 + P351 + P338 P308 + P313 P321 P330 P332 + P313 P337 + P313 P362 P403 + P233 P405 P501	Do not handle until all safety precautions have been read and understood. Avoid breathing dust/fume/gas/mist/vapors/spray. Wash skin thoroughly after handling Do not eat, drink or smoke when using this product. Use only outdoors or in a well-ventilated area. Wear protective gloves/eye protection/face protection. IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell. IF ON SKIN: Wash with plenty of soap and water. IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. IF exposed or concerned: Get medical advice/attention. Specific treatment (see supplemental first aid instructions on this label). Rinse mouth. If skin irritation occurs: Get medical advice/attention. If eye irritation persists: Get medical advice/attention. Take off contaminated clothing and wash before reuse. Store in a well-ventilated place. Keep container tightly closed. Store locked up. Dispose of contents/container to an approved waste disposal plant.


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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
Decitabine	Decitabine	50 mg	2353-33-5	N/A
Monobasic potassium phosphate, USP NF	Monobasic potassium phosphate, USP-NF	68 mg	7778-77-0	N/A
Sodium hydroxide, USP-NF	Sodium hydroxide, NF	11.6 mg <i>and</i> q.s. Adjust to pH 6.8 to 7.2	1310-73-2	N/A
Hydrochloric Acid, USP-NF	Hydrochloric Acid, USP-NF	q.s. Adjust to pH 6.8 to 7.2	7647-01-0	N/A
Nitrogen, USP-NF	Nitrogen, USP-NF	As required	93037-13-9	N/A

### Section 4 - First Aid Measures

- Eye Exposure:** Remove any contact lenses, locate eye-wash station, and flush eyes immediately with large amounts of water. Separate eyelids with fingers to ensure adequate flushing. Promptly call a physician.
- Skin Exposure:** Rinse skin thoroughly with large amounts of water. Remove contaminated clothing and shoes and call a physician.
- Ingestion:** Wash out mouth with water; Do NOT induce vomiting; call a physician.
- Inhalation:** Immediately relocate self or casualty to fresh air. If breathing is difficult, give cardiopulmonary resuscitation (CPR). Avoid mouth-to-mouth resuscitation.
- 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, dry chemical, foam, and carbon dioxide fire extinguisher.
- (b) **Hazardous Combustion Products:** During combustion, may emit irritant fumes.
- (c) **Special Protective Equipment / Precautions:** Wear self-contained breathing apparatus and protective clothing.

### Section 6 - Accidental Release Measures

- Personal precautions, protective equipment and emergency procedures:** Use personal protective equipment. Avoid dust formation. Avoid breathing vapors, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.
- Release to Air:** N/A
- Release to Water:** Prevent further leakage or spillage if safe to do so. Do not let product enter drains.

### Section 7 - Handling and Storage

- General Handling:** Avoid contact with skin and eyes. Avoid formation of dust and aerosols. Provide appropriate exhaust ventilation at places where dust is formed.
- Storage Conditions:** Store at 20° to 25°C (68° to 77°F); excursions permitted between 15° and 30°C (59° and 86°F). [See USP Controlled Room Temperature.] Discard unused portion.  
**Keep this and all medications out of the reach of children.**

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### Section 8 - Exposure Controls / Personal Protection

**(a) Exposure Limits**

Compound	Issuer	Type	Exposure Limit
Decitabine	N/A	N/A	This product does not contain any hazardous materials with occupational exposure limits established by the region-specific regulatory bodies.

**(b) Engineering Controls**


Ensure adequate ventilation. Provide accessible safety shower and eye wash station.

**(c) Individual Protection Measures**

<b>Respiratory Protection:</b>	Suitable respirator.
<b>Eye Protection:</b>	Safety goggles with side-shields.
<b>Skin Protection:</b>	Impervious clothing.
<b>Other Protective Equipment:</b>	Protective gloves.
<b>Additional Exposure Precautions:</b>	Keep the product away from drains, water courses or the soil. Clean spillages in a safe way as soon as possible.

### Section 9 - Physical and Chemical Properties

<b>(a) Appearance</b>	White to almost white lyophilized powder
<b>(b) Odor</b>	N/A
<b>(c) Odor Threshold</b>	N/A
<b>(d) pH</b>	N/A
<b>(e) Melting Point:</b>	Melting point/range: 200 °C (392 °F)
<b>(f) Initial Boiling Point:</b>	N/A
<b>(g) Flash Point</b>	N/A
<b>(h) Evaporation Rate:</b>	N/A

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<b>(i)</b>	<b>Flammability</b>	N/A
<b>(j)</b>	<b>Upper Lower Flammability or Explosion Limits</b>	N/A
<b>(k)</b>	<b>Vapor Pressure:</b>	N/A
<b>(l)</b>	<b>Vapor Density:</b>	N/A
<b>(m)</b>	<b>Relative Density</b>	N/A
<b>(n)</b>	<b>Solubility(ies)</b>	Soluble in water.
<b>(o)</b>	<b>Partition Coefficient: n-octanol/water</b>	N/A
<b>(p)</b>	<b>Auto-ignition Temperature</b>	N/A
<b>(q)</b>	<b>Decomposition Temperature</b>	N/A
<b>(r)</b>	<b>Viscosity</b>	N/A

### Section 10 - Stability and Reactivity


<b>(a)</b>	<b>Reactivity</b>	Stable under recommended storage conditions.
<b>(b)</b>	<b>Chemical Stability</b>	Stable under standard use and storage conditions.
<b>(c)</b>	<b>Possibility of Hazardous Reactions</b>	Not know to occur
<b>(d)</b>	<b>Conditions to Avoid</b>	Strong oxidants and heat.
<b>(e)</b>	<b>Incompatible Materials</b>	Strong acids/alkalis, strong oxidizing/reducing agents.
<b>(f)</b>	<b>Hazardous Decomposition Products</b>	Under fire conditions, may decompose and emit toxic fumes.

### Section 11 Toxicological Information

<b>(a)</b>	<b>Likely Routes of Exposure</b>	Ingestion, Inhalation, skin, eye
<b>(b)</b>	<b>Symptoms related to the physical, chemical and toxicological</b>	Product does not present an acute toxicity hazard based on known or supplied information.
<b>(c)</b>	<b>Delayed and immediate effects and also chronic effects from short and long term exposure</b>	N/A

**(d) Acute Toxicity**

N/A

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**(e) Hazardous Chemical Listings**

NTP: No      IARC: No      OSHA: Listed      NIOSH: Listed Group 1:  
 Antineoplastic drugs, including those with the manufacture's safe handling guidance  
 (MSHG)

**Section 12 - Ecological Information**

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

**Section 13 - Disposal Considerations**

**Waste Disposal:**


Offer surplus and non-recyclable solutions to a licensed disposal company. Contact a licensed professional waste disposal service to dispose of this material. Dissolve or mix the material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber.

**Contaminated packaging**

Dispose of as unused product.

**Section 14 - Transport Information**

<b>(a)</b>	<b>UN Number</b>	Not available
<b>(b)</b>	<b>UN Proper Shipping Name</b>	Not available
<b>(c)</b>	<b>Transport Hazard Class(es)</b>	Not available
<b>(d)</b>	<b>Packing Group</b>	Not available
<b>(e)</b>	<b>Environmental Hazards</b>	Not available
<b>(f)</b>	<b>Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code)</b>	Not available
<b>(g)</b>	<b>Special Precautions</b>	Not available

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**DOT:** Not Regulated  
**ICAO/IATA:** Not Regulated  
**IMO:** Not Regulated

### 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 on this list  
 CERCLA - Not on this list  
 SARA 311/312 Hazards - Acute Health Hazard, Chronic Health Hazard  
 SARA 313 - Not on this list  
 SARA 302 – Not on this list  
 RCRA listed – Not listed

California Proposition 65 –Not on this list

### 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 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:

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 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



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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
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

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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