
	Sagent Pharmaceuticals, Inc.		
	Document Type Safety Data Sheet (SDS)	Document Title Decitabine	
	Document No. MSDS-0092	Version 2.0	Effective Date 8/30/2018


Section 1 - Identification

- (a) **Product Identifier:** Decitabine
- (b) **Product Code:** 25021-231-20
- Common/Trade Name:** Dacogen
- Chemical Name:** 4-amino-1-((2R,4S,5R)-4-hydroxy-5-(hydroxymethyl) tetrahydrofuran-2-yl)-1,3,5-triazin-2(1H)-one
- Chemical Family:** Cytidine antimetabolite
- (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:** 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:** 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) Signal Word, Hazard statement(s), Symbol(s), and/or Precautionary statement(s):	(c) Description of Hazards:
	- <u>Signal Word:</u> 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	5.30 mg/g	2353-33-5	N/A
Monobasic potassium phosphate, NF	Monobasic potassium phosphate, NF	7.21 mg/g	7778-77-0	N/A
Sodium hydroxide, NF	Sodium hydroxide, NF	1.23 mg/g	1310-73-2	N/A
Acetonitrile, HP	Acetonitrile, HP	29.0 % (w/w)	75-05-8	N/A
Tert-butyl alcohol	Tert-butyl alcohol	0.8% (w/w)	75-65-0	N/A
Water for Injection, USP	Water for Injection, USP	q.s. to target weight	7789-20-0	N/A
Nitrogen, NF	Nitrogen, 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: Keep container tightly closed in a dry and well-ventilated place. Store vials at 25°C (77°F), Excursions permitted to 15-30°C (59-86°F).

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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

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

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Section 9 - Physical and Chemical Properties

(a)	Appearance	White to off-white (Solid)
(b)	Odor	N/A
(c)	Odor Threshold	N/A
(d)	pH	N/A
(e)	Melting Point:	Melting point/range: 200 °C (392 °F)
(f)	Initial Boiling Point:	N/A
(g)	Flash Point	N/A
(h)	Evaporation Rate:	N/A
(i)	Flammability	N/A
(j)	Upper Lower Flammability or Explosion Limits	N/A
(k)	Vapor Pressure:	N/A
(l)	Vapor Density:	N/A
(m)	Relative Density	N/A
(n)	Solubility(ies)	Soluble in water.
(o)	Partition Coefficient: n-octanol/water	N/A
(p)	Auto-ignition Temperature	N/A
(q)	Decomposition Temperature	N/A
(r)	Viscosity	N/A

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Section 10 - Stability and Reactivity

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

Section 11 - Toxicological Information

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

(d) Acute Toxicity


N/A

(e) Hazardous Chemical Listings

NTP: No

IARC: No

OSHA: No

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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:

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

(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

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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 – 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

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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:

Sagent Pharmaceuticals, Inc.
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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

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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