

# Decitabine for Injection

## Safety Data Sheet

### SECTION 1: Identification

#### 1.1. Identification

Product name : Decitabine for Injection  
Other means of identification : 50 mg per single dose vial, NDC 55150-376-01

#### 1.2. Relevant identified uses of the substance or mixture and uses advised against

Use of the substance/mixture : Pharmaceutical

#### 1.3. Details of the supplier of the safety data sheet

AuroMedics  
279 Princeton Highstown Road  
East Windsor, NJ 08520

#### 1.4. Emergency telephone number

Emergency number : 1-888-238-7880

### SECTION 2: Hazard(s) identification

#### 2.1. Classification of the substance or mixture

##### GHS US classification

Acute Tox. 4 (Oral) H302  
Skin Corr. 1A H314  
Eye Dam. 1 H318  
Muta. 2 H341  
Repr. 1B H360  
STOT SE 3 H335

Full text of hazard classes and H-statements : see section 16

#### 2.2. Label elements

##### GHS US labeling

Hazard pictograms (GHS US) :



GHS05

GHS07

GHS08

Signal word (GHS US) :

Danger

Hazard statements (GHS US) :

H302 - Harmful if swallowed  
H314 - Causes severe skin burns and eye damage  
H318 - Causes serious eye damage  
H335 - May cause respiratory irritation  
H341 - Suspected of causing genetic defects  
H360 - May damage fertility or the unborn child

Precautionary statements (GHS US) :

P201 - Obtain special instructions before use.  
P202 - Do not handle until all safety precautions have been read and understood.  
P260 - Do not breathe dust/fume/gas/mist/vapors/spray.  
P261 - Avoid breathing dust/fume/gas/mist/vapors/spray.  
P264 - Wash hands, forearms and face thoroughly after handling.  
P270 - Do not eat, drink or smoke when using this product.  
P271 - Use only outdoors or in a well-ventilated area.  
P280 - Wear protective gloves/protective clothing/eye protection/face protection.  
P301+P312 - If swallowed: Call a poison center or doctor if you feel unwell.  
P301+P330+P331 - If swallowed: rinse mouth. Do NOT induce vomiting.  
P303+P361+P353 - If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.  
P304+P340 - If inhaled: Remove person to fresh air and keep comfortable for breathing.  
P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
P308+P313 - If exposed or concerned: Get medical advice/attention.  
P310 - Immediately call a poison center or doctor.  
P312 - Call a poison center or doctor if you feel unwell.  
P321 - Specific treatment (see supplemental first aid instruction on this label).

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P330 - Rinse mouth.  
P363 - Wash contaminated clothing before reuse.  
P403+P233 - Store in a well-ventilated place. Keep container tightly closed.  
P405 - Store locked up.  
P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

### 2.3. Other hazards

No additional information available

### 2.4. Unknown acute toxicity (GHS US)

Not applicable

## SECTION 3: Composition/Information on ingredients

### 3.1. Substances

Not applicable

### 3.2. Mixtures

Name	Product identifier	%	GHS US classification
Phosphoric acid, potassium salt (1:1)	(CAS-No.) 7778-77-0	52.5	Not classified
5-Aza-2'-deoxycytidine	(CAS-No.) 2353-33-5	38.6	Acute Tox. 4 (Oral), H302 Skin Irrit. 2, H315 Eye Irrit. 2A, H319 Muta. 2, H341 Repr. 1B, H360 STOT SE 3, H335
Sodium hydroxide	(CAS-No.) 1310-73-2	9	Met. Corr. 1, H290 Skin Corr. 1A, H314 Eye Dam. 1, H318
Hydrochloric acid	(CAS-No.) 7647-01-0	< 1	Skin Corr. 1, H314 Eye Dam. 1, H318

Full text of hazard classes and H-statements : see section 16

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

First-aid measures after inhalation : If not breathing, give artificial respiration.  
First-aid measures after skin contact : Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.  
First-aid measures after eye contact : In case of dust contact with eyes, rinse immediately with plenty of water.  
First-aid measures after ingestion : Go into open air and ventilate suspected area.

### 4.2. Most important symptoms and effects, both acute and delayed

Symptoms/effects after inhalation : May cause respiratory irritation.  
Symptoms/effects after skin contact : Causes severe skin burns.  
Symptoms/effects after eye contact : Causes eye damage.  
Symptoms/effects after ingestion : May be harmful if swallowed.

### 4.3. Indication of any immediate medical attention and special treatment needed

No additional information available

## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

Suitable extinguishing media : Use extinguishing media appropriate for surrounding fire.  
Unsuitable extinguishing media : None.

### 5.2. Special hazards arising from the substance or mixture

Fire hazard : None known.

### 5.3. Advice for firefighters

Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

## SECTION 6: Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

General measures : No special measures required.

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### 6.1.1. For non-emergency personnel

No additional information available

### 6.1.2. For emergency responders

## 6.2. Environmental precautions

Prevent entry to sewers and public waters.

## 6.3. Methods and material for containment and cleaning up

For containment : Stop the flow of material, if this is without risk.  
Methods for cleaning up : Place in a suitable container and dispose according to local, state and federal regulations.

## 6.4. Reference to other sections

No additional information available

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

Precautions for safe handling : Do not eat, drink or smoke when using this product.

### 7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store vials at 20°C to 25°C (68°F to 77°F)

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

Hydrochloric acid (7647-01-0)		
ACGIH	ACGIH OEL Ceiling [ppm]	2 ppm
OSHA	OSHA PEL (Ceiling)	7 mg/m <sup>3</sup>
OSHA	OSHA PEL C [ppm]	5 ppm
IDLH	IDLH [ppm]	50 ppm
NIOSH	NIOSH REL (Ceiling)	7 mg/m <sup>3</sup>
NIOSH	NIOSH REL C [ppm]	5 ppm
Sodium hydroxide (1310-73-2)		
ACGIH	ACGIH OEL Ceiling	2 mg/m <sup>3</sup>
OSHA	OSHA PEL (TWA) [1]	2 mg/m <sup>3</sup>
IDLH	IDLH	10 mg/m <sup>3</sup>
NIOSH	NIOSH REL (Ceiling)	2 mg/m <sup>3</sup>
Phosphoric acid, potassium salt (1:1) (7778-77-0)		
Not applicable		
5-Aza-2'-deoxycytidine (2353-33-5)		
Not applicable		

### 8.2. Exposure controls

Appropriate engineering controls : Local exhaust and general ventilation must be adequate to meet exposure standards.  
Hand protection : Use neoprene or rubber gloves.  
Eye protection : In case of dust production: protective goggles.  
Skin and body protection : Wear suitable working clothes.  
Respiratory protection : Wear NIOSH approved respirator when handling.

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

Physical state : Solid  
Appearance : Lyophilized cake or powder  
Color : White to off-white

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Odor	: Odorless
Odor threshold	: No data available
pH	: No data available
Melting point	: No data available
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Relative evaporation rate (butyl acetate=1)	: No data available
Flammability (solid, gas)	: No data available
Vapor pressure	: No data available
Relative vapor density at 20 °C	: No data available
Relative density	: No data available
Solubility	: No data available
Partition coefficient n-octanol/water (Log Pow)	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosion limits	: No data available
Explosive properties	: No data available
Oxidizing properties	: No data available

### 9.2. Other information

No additional information available

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

No additional information available

### 10.2. Chemical stability

The product is stable at normal handling and storage conditions.

### 10.3. Possibility of hazardous reactions

Will not occur.

### 10.4. Conditions to avoid

Air contact.

### 10.5. Incompatible materials

None known.

### 10.6. Hazardous decomposition products

None known.

## SECTION 11: Toxicological information

### 11.1. Information on toxicological effects

Acute toxicity : Not classified

Decitabine for Injection	
ATE US (oral)	1295.337 mg/kg body weight
Hydrochloric acid (7647-01-0)	
LD50 oral rat	238 – 277 mg/kg
LD50 dermal rabbit	> 5010 mg/kg
LC50 Inhalation - Rat	1.68 mg/l (Exposure time: 1 h)
ATE US (oral)	238 mg/kg body weight
ATE US (vapors)	1.68 mg/l/4h
ATE US (dust, mist)	1.68 mg/l/4h
Sodium hydroxide (1310-73-2)	
LD50 oral rat	140 – 340 mg/kg

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Sodium hydroxide (1310-73-2)	
LD50 dermal rabbit	1350 mg/kg
ATE US (dermal)	1350 mg/kg

Phosphoric acid, potassium salt (1:1) (7778-77-0)	
LD50 oral rat	3200 mg/kg

5-Aza-2'-deoxycytidine (2353-33-5)	
ATE US (oral)	500 mg/kg body weight

Skin corrosion/irritation	: Causes severe skin burns.
Serious eye damage/irritation	: Causes serious eye damage.
Respiratory or skin sensitization	: Not classified
Germ cell mutagenicity	: Suspected of causing genetic defects.
Carcinogenicity	: Not classified

Hydrochloric acid (7647-01-0)	
IARC group	3 - Not classifiable

Reproductive toxicity	: May damage fertility or the unborn child.
STOT-single exposure	: May cause respiratory irritation.
STOT-repeated exposure	: Not classified
Aspiration hazard	: Not classified

## SECTION 12: Ecological information

### 12.1. Toxicity

Sodium hydroxide (1310-73-2)	
LC50 - Fish [1]	45.4 mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])

### 12.2. Persistence and degradability

No additional information available

### 12.3. Bioaccumulative potential

No additional information available

### 12.4. Mobility in soil

No additional information available

### 12.5. Other adverse effects

No additional information available

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

Product/Packaging disposal recommendations : Dispose of contents/container in accordance with local/regional/national/international regulations.

## SECTION 14: Transport information

### Department of Transportation (DOT)

In accordance with DOT

Not applicable

## SECTION 15: Regulatory information

### 15.1. US Federal regulations

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### Hydrochloric acid (7647-01-0)

Listed on the United States TSCA (Toxic Substances Control Act) inventory  
Listed on the United States SARA Section 302  
Subject to reporting requirements of United States SARA Section 313

CERCLA RQ	5000 lb
SARA Section 302 Threshold Planning Quantity (TPQ)	500 lb (gas only)
SARA Section 313 - Emission Reporting	1 % (acid aerosols including mists, vapors, gas, fog, and other airborne forms of any particle size)

### Sodium hydroxide (1310-73-2)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

CERCLA RQ	1000 lb
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### Phosphoric acid, potassium salt (1:1) (7778-77-0)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

## 15.2. US State regulations

### Hydrochloric acid (7647-01-0)

U.S. - Massachusetts - Right To Know List  
U.S. - Minnesota - Hazardous Substance List  
U.S. - New Jersey - Right to Know Hazardous Substance List  
U.S. - Pennsylvania - RTK (Right to Know) List

### Sodium hydroxide (1310-73-2)

U.S. - Massachusetts - Right To Know List  
U.S. - Minnesota - Hazardous Substance List  
U.S. - New Jersey - Right to Know Hazardous Substance List  
U.S. - Pennsylvania - RTK (Right to Know) List

## SECTION 16: Other information

Full text of H-phrases:

Acute Tox. 4 (Oral)	Acute toxicity (oral) Category 4
Eye Dam. 1	Serious eye damage/eye irritation Category 1
Eye Irrit. 2A	Serious eye damage/eye irritation Category 2A
Met. Corr. 1	Corrosive to metals Category 1
Muta. 2	Germ cell mutagenicity Category 2
Repr. 1B	Reproductive toxicity Category 1B
Skin Corr. 1	Skin corrosion/irritation Category 1
Skin Corr. 1A	Skin corrosion/irritation Category 1A
Skin Irrit. 2	Skin corrosion/irritation Category 2
STOT SE 3	Specific target organ toxicity — Single exposure, Category 3, Respiratory tract irritation
H290	May be corrosive to metals
H302	Harmful if swallowed
H314	Causes severe skin burns and eye damage
H315	Causes skin irritation
H318	Causes serious eye damage
H319	Causes serious eye irritation
H335	May cause respiratory irritation
H341	Suspected of causing genetic defects
H360	May damage fertility or the unborn child

*This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.*