

SDS Title: Cytarabine Injection Safety Data Sheet	SDS Number: SDS-000004	Page Number: Page 1 of 10
Function: Regulatory Affairs	Effective Date: August 02, 2018	Version Number: 1.0

SECTION 1: IDENTIFICATION

1.1. Product Identifier

Product Form: Mixture

Product Name: Cytarabine Injection 100mg/mL

1.2. Intended Use of the Product

Use of the Substance/Mixture: Pharmaceutical, use only as directed. Refer to product insert for product information and usage instructions. Antineoplastic. For professional use only.

1.3. Name, Address, and Telephone of the Responsible Party

Company

Meitheal Pharmaceuticals, Inc.
8700 W. Bryn Mawr, Suite 600S
Chicago, IL 60631
224-443-4617

www.meithealpharma.com

1.4. Emergency Telephone Number

Emergency Number : 844-824-8426

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the Substance or Mixture

Skin Sens. 1 H317

Repr. 2 H361

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

2.2. Label Elements

GHS-US Labeling

Hazard Pictograms (GHS-US) :



Signal Word (GHS-US) : Warning

Hazard Statements (GHS-US) : H317 - May cause an allergic skin reaction.
H361 - Suspected of damaging 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.
P261 - Avoid breathing vapors, mist, or spray.
P272 - Contaminated work clothing must not be allowed out of the workplace.
P280 - Wear protective gloves, protective clothing, and eye protection.
P302+P352 - If on skin: Wash with plenty of water.
P308+P313 - If exposed or concerned: Get medical advice/attention.
P321 - Specific treatment (see section 4 on this SDS).
P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.
P363 - Wash contaminated clothing before reuse.



Meitheal Pharmaceuticals, Inc.

Safety Data Sheet

SDS Title: Cytarabine Injection Safety Data Sheet	SDS Number: SDS-000004	Page Number: Page 2 of 10
Function: Regulatory Affairs	Effective Date: August 02, 2018	Version Number: 1.0

P405 - Store locked up.

P501 - Dispose of contents/container in accordance with local, regional, national, and international regulations.

2.3. Other Hazards

Exposure may aggravate pre-existing eye, skin, or respiratory conditions.

2.4. Unknown Acute Toxicity (GHS-US)

No data available

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS**3.1. Substance**

Not applicable

3.2. Mixture

Name	Product Identifier	%	GHS-US classification
Water	(CAS-No.) 7732-18-5	89.9	Not classified
Cytarabine	(CAS-No.) 147-94-4	10	Skin Sens. 1, H317 Repr. 2, H361
Sodium hydroxide	(CAS-No.) 1310-73-2	< 0.1	Met. Corr. 1, H290 Acute Tox. 3 (Oral), H301 Skin Corr. 1A, H314 Eye Dam. 1, H318 Aquatic Acute 3, H402
Hydrochloric acid	(CAS-No.) 7647-01-0	< 0.1	Press. Gas (Comp.), H280 Acute Tox. 3 (Inhalation:gas), H331 Skin Corr. 1A, H314 Eye Dam. 1, H318 STOT SE 3, H335 Aquatic Acute 1, H400

Full text of H-phrases: see section 16

SECTION 4: FIRST AID MEASURES**4.1. Description of First-aid Measures**

First-aid Measures General: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

First-aid Measures After Inhalation: When symptoms occur: go into open air and ventilate suspected area. Obtain medical attention if breathing difficulty persists.

First-aid Measures After Skin Contact: Remove contaminated clothing. If exposed or concerned: Get medical advice/attention. Drench affected area with water for at least 15 minutes. Obtain medical attention if irritation/rash develops or persists.

First-aid Measures After Eye Contact: Remove contact lenses, if present and easy to do. Continue rinsing. Rinse cautiously with water for at least 15 minutes. Obtain medical attention.

First-aid Measures After Ingestion: Rinse mouth. Do NOT induce vomiting. Obtain medical attention.

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SDS Title: Cytarabine Injection Safety Data Sheet	SDS Number: SDS-000004	Page Number: Page 3 of 10
Function: Regulatory Affairs	Effective Date: August 02, 2018	Version Number: 1.0

4.2. Most Important Symptoms and Effects Both Acute and Delayed

Symptoms/Injuries: Suspected of damaging fertility or the unborn child. Skin sensitization.

Symptoms/Injuries After Inhalation: Prolonged exposure may cause irritation.

Symptoms/Injuries After Skin Contact: May cause an allergic skin reaction.

Symptoms/Injuries After Eye Contact: May cause slight irritation to eyes.

Symptoms/Injuries After Ingestion: Ingestion may cause adverse effects.

Chronic Symptoms: Suspected of damaging fertility or the unborn child.

4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed

If exposed or concerned, get medical advice and attention. If medical advice is needed, have product container or label at hand. In the event of accidental injection, immediately call a poison center or seek medical advice.

SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing Media

Suitable Extinguishing Media: Water spray, fog, carbon dioxide (CO₂), alcohol-resistant foam, or dry chemical.

Unsuitable Extinguishing Media: Do not use a heavy water stream. Use of heavy stream of water may spread fire.

5.2. Special Hazards Arising From the Substance or Mixture

Fire Hazard: Not considered flammable but may burn at high temperatures.

Explosion Hazard: Product is not explosive.

Reactivity: Hazardous reactions will not occur under normal conditions.

5.3. Advice for Firefighters

Precautionary Measures Fire: Exercise caution when fighting any chemical fire.

Firefighting Instructions: Use water spray or fog for cooling exposed containers.

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

Hazardous Combustion Products: Nitrogen oxides. Carbon oxides (CO, CO₂).

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures

General Measures: Do not get in eyes, on skin, or on clothing. Do not breathe vapor, mist or spray.

6.1.1. For Non-Emergency Personnel

Protective Equipment: Use appropriate personal protective equipment (PPE).

Emergency Procedures: Evacuate unnecessary personnel.

6.1.2. For Emergency Personnel

Protective Equipment: Equip cleanup crew with proper protection.

Emergency Procedures: Upon arrival at the scene, a first responder is expected to recognize the presence of dangerous goods, protect oneself and the public, secure the area, and call for the assistance of trained personnel as soon as conditions permit. Ventilate area.

6.2. Environmental Precautions

Prevent entry to sewers and public waters.

6.3. Methods and Materials for Containment and Cleaning Up

For Containment: Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams.

Methods for Cleaning Up: Clean up spills immediately and dispose of waste safely. Transfer spilled material to a suitable container for disposal. Contact competent authorities after a spill.



Meitheal Pharmaceuticals, Inc.

Safety Data Sheet

SDS Title: Cytarabine Injection Safety Data Sheet	SDS Number: SDS-000004	Page Number: Page 4 of 10
Function: Regulatory Affairs	Effective Date: August 02, 2018	Version Number: 1.0

6.4. Reference to Other Sections

See Section 8 for exposure controls and personal protection and Section 13 for disposal considerations.

SECTION 7: HANDLING AND STORAGE**7.1. Precautions for Safe Handling**

Precautions for Safe Handling: Do NOT breathe (dust, vapor, mist, gas). Do not get in eyes, on skin, or on clothing. Do not handle until all safety precautions have been read and understood. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Obtain special instructions before use.

Hygiene Measures: Handle in accordance with good industrial hygiene and safety procedures.

7.2. Conditions for Safe Storage, Including Any Incompatibilities

Technical Measures: Comply with applicable regulations.

Storage Conditions: Keep container closed when not in use. Store in a dry, cool place. Store locked up/in a secure area. Keep/Store away from direct sunlight, extremely high or low temperatures and incompatible materials.

Incompatible Materials: Strong acids, strong bases, strong oxidizers.

7.3. Specific End Use(s)

Pharmaceutical, use only as directed. Refer to product insert for product information and usage instructions. Antineoplastic. For professional use only.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**8.1. Control Parameters**

For substances listed in section 3 that are not listed here, there are no established exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), AIHA (WEEL), NIOSH (REL), or OSHA (PEL).

Sodium hydroxide (1310-73-2)

USA ACGIH	ACGIH Ceiling (mg/m ³)	2 mg/m ³
USA NIOSH	NIOSH REL (ceiling) (mg/m ³)	2 mg/m ³
USA IDLH	US IDLH (mg/m ³)	10 mg/m ³
USA OSHA	OSHA PEL (TWA) (mg/m ³)	2 mg/m ³

Hydrochloric acid (7647-01-0)

USA ACGIH	ACGIH Ceiling (ppm)	2 ppm
USA ACGIH	ACGIH chemical category	Not Classifiable as a Human Carcinogen
USA NIOSH	NIOSH REL (ceiling) (mg/m ³)	7 mg/m ³
USA NIOSH	NIOSH REL (ceiling) (ppm)	5 ppm
USA IDLH	US IDLH (ppm)	50 ppm
USA OSHA	OSHA PEL (Ceiling) (mg/m ³)	7 mg/m ³
USA OSHA	OSHA PEL (Ceiling) (ppm)	5 ppm

8.2. Exposure Controls

Appropriate Engineering Controls : Suitable eye/body wash equipment should be available in the vicinity of any potential exposure. Ensure adequate ventilation, especially in confined areas. Ensure all national/local regulations are observed.

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SDS Title: Cytarabine Injection Safety Data Sheet	SDS Number: SDS-000004	Page Number: Page 5 of 10
Function: Regulatory Affairs	Effective Date: August 02, 2018	Version Number: 1.0

Personal Protective Equipment

: Gloves. Protective clothing. Protective goggles. Insufficient ventilation: wear respiratory protection.


Materials for Protective Clothing

: Chemically resistant materials and fabrics.

Hand Protection

: Wear protective gloves.

Eye and Face Protection

: Chemical safety goggles.

Skin and Body Protection

: Wear suitable protective clothing.

Respiratory Protection

: If exposure limits are exceeded or irritation is experienced, approved respiratory protection should be worn. In case of inadequate ventilation, oxygen deficient atmosphere, or where exposure levels are not known wear approved respiratory protection.

Other Information

: When using, do not eat, drink or smoke.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES
9.1. Information on Basic Physical and Chemical Properties

Physical State	: Liquid
Appearance	: Clear, colorless slight yellow solution
Odor	: Odorless
Odor Threshold	: No data available
pH	: 7.0 - 9.5
Evaporation Rate	: No data available
Melting Point	: No data available
Freezing Point	: No data available
Boiling Point	: No data available
Flash Point	: No data available
Auto-ignition Temperature	: No data available
Decomposition Temperature	: No data available
Flammability (solid, gas)	: Not applicable
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	: No data available
Viscosity	: No data available

9.2. Other Information No additional information available

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity: Hazardous reactions will not occur under normal conditions.

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Meitheal Pharmaceuticals, Inc.

Safety Data Sheet

SDS Title: Cytarabine Injection Safety Data Sheet	SDS Number: SDS-000004	Page Number: Page 6 of 10
Function: Regulatory Affairs	Effective Date: August 02, 2018	Version Number: 1.0

- 10.2. **Chemical Stability:** Stable under recommended handling and storage conditions (see section 7).
- 10.3. **Possibility of Hazardous Reactions:** Hazardous polymerization will not occur.
- 10.4. **Conditions to Avoid:** Direct sunlight, extremely high or low temperatures, and incompatible materials.
- 10.5. **Incompatible Materials:** Strong acids, strong bases, strong oxidizers.
- 10.6. **Hazardous Decomposition Products:** Nitrogen oxides. Carbon oxides (CO, CO₂).

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on Toxicological Effects

Acute Toxicity: Not classified

Cytarabine (147-94-4)	
LD50 Oral Rat	> 5 g/kg
Sodium hydroxide (1310-73-2)	
LD50 Oral Rat	140 - 340 mg/kg
Hydrochloric acid (7647-01-0)	
LD50 Oral Rat	238 (238 - 277) mg/kg
LD50 Dermal Rabbit	> 5010 mg/kg
LC50 Inhalation Rat	1.68 mg/l (Exposure time: 1 h)
LC50 Inhalation Rat	1411 ppm
LC50 Inhalation Rat	0.42 mg/l/4h
ATE (Gases)	700.00 ppmV/4h

Skin Corrosion/Irritation: Not classified

pH: 7.0 - 9.5

Serious Eye Damage/Irritation: Not classified

pH: 7.0 - 9.5

Respiratory or Skin Sensitization: May cause an allergic skin reaction.

Germ Cell Mutagenicity: Not classified

Carcinogenicity: Not classified

Hydrochloric acid (7647-01-0)	
IARC group	3

Reproductive Toxicity: Suspected of damaging fertility or the unborn child.

Specific Target Organ Toxicity (Single Exposure): Not classified

Specific Target Organ Toxicity (Repeated Exposure): Not classified

Aspiration Hazard: Not classified

Symptoms/Injuries After Inhalation: Prolonged exposure may cause irritation.

Symptoms/Injuries After Skin Contact: May cause an allergic skin reaction.

Symptoms/Injuries After Eye Contact: May cause slight irritation to eyes.

Symptoms/Injuries After Ingestion: Ingestion may cause adverse effects.

Chronic Symptoms: Suspected of damaging fertility or the unborn child.



Meitheal Pharmaceuticals, Inc.

Safety Data Sheet

SDS Title: Cytarabine Injection Safety Data Sheet	SDS Number: SDS-000004	Page Number: Page 7 of 10
Function: Regulatory Affairs	Effective Date: August 02, 2018	Version Number: 1.0

SECTION 12: ECOLOGICAL INFORMATION**12.1. Toxicity**

Ecology - General : Not classified.

Sodium hydroxide (1310-73-2)	
LC50 Fish 1	45.4 mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])
EC50 Daphnia 1	40 mg/l
Hydrochloric acid (7647-01-0)	
EC50 Daphnia 1	0.492 mg/l

12.2. Persistence and Degradability

Cytarabine Injection 100mg/mL	
Persistence and Degradability	Not established.

12.3. Bioaccumulative Potential

Cytarabine Injection 100mg/mL	
Bioaccumulative Potential	Not established.

12.4. Mobility in Soil No additional information available**12.5. Other Adverse Effects**

Other Information : Avoid release to the environment.

SECTION 13: DISPOSAL CONSIDERATIONS**13.1. Waste Treatment Methods**

Waste Disposal Recommendations: Dispose of contents/container in accordance with local, regional, national, and international regulations.

Additional Information: Container may remain hazardous when empty. Continue to observe all precautions.

Ecology - Waste Materials: Avoid release to the environment.

SECTION 14: TRANSPORT INFORMATION

The shipping description(s) stated herein were prepared in accordance with certain assumptions at the time the SDS was authored, and can vary based on a number of variables that may or may not have been known at the time the SDS was issued.

14.1. In Accordance with DOT Not regulated for transport**14.2. In Accordance with IMDG** Not regulated for transport**14.3. In Accordance with IATA** Not regulated for transport**SECTION 15: REGULATORY INFORMATION****15.1. US Federal Regulations**

Cytarabine Injection 100mg/mL	
SARA Section 311/312 Hazard Classes	Health hazard - Reproductive toxicity Health hazard - Respiratory or skin sensitization
Sodium hydroxide (1310-73-2)	

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Meitheal Pharmaceuticals, Inc.

Safety Data Sheet

SDS Title: Cytarabine Injection Safety Data Sheet	SDS Number: SDS-000004	Page Number: Page 8 of 10
Function: Regulatory Affairs	Effective Date: August 02, 2018	Version Number: 1.0

Listed on the United States TSCA (Toxic Substances Control Act) inventory	
CERCLA RQ	1000 lb
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)
Water (7732-18-5)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	

15.2. US State Regulations

Cytarabine (147-94-4)	
U.S. - California - Proposition 65 - Developmental Toxicity	WARNING: This product contains chemicals known to the State of California to cause birth defects.
Cytarabine (147-94-4)	
U.S. - Massachusetts - Right To Know List	
Sodium hydroxide (1310-73-2)	
U.S. - Massachusetts - Right To Know List	
U.S. - New Jersey - Right to Know Hazardous Substance List	
U.S. - Pennsylvania - RTK (Right to Know) - Environmental Hazard List	
U.S. - Pennsylvania - RTK (Right to Know) List	
Hydrochloric acid (7647-01-0)	
U.S. - Massachusetts - Right To Know List	
U.S. - New Jersey - Right to Know Hazardous Substance List	
U.S. - Pennsylvania - RTK (Right to Know) - Environmental Hazard List	
U.S. - Pennsylvania - RTK (Right to Know) List	

SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

Date of Preparation or Latest Revision : 08/02/2018
 Other Information : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200

GHS Full Text Phrases:

Acute Tox. 3 (Inhalation:gas)	Acute toxicity (inhalation:gas) Category 3
Acute Tox. 3 (Oral)	Acute toxicity (oral) Category 3

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Meitheal Pharmaceuticals, Inc.

Safety Data Sheet

SDS Title: Cytarabine Injection Safety Data Sheet	SDS Number: SDS-000004	Page Number: Page 9 of 10
Function: Regulatory Affairs	Effective Date: August 02, 2018	Version Number: 1.0

Aquatic Acute 1	Hazardous to the aquatic environment - Acute Hazard Category 1
Aquatic Acute 3	Hazardous to the aquatic environment - Acute Hazard Category 3
Eye Dam. 1	Serious eye damage/eye irritation Category 1
Met. Corr. 1	Corrosive to metals Category 1
Press. Gas (Comp.)	Gases under pressure Compressed gas
Repr. 2	Reproductive toxicity Category 2
Skin Corr. 1A	Skin corrosion/irritation Category 1A
Skin Sens. 1	Skin sensitization, Category 1
STOT SE 3	Specific target organ toxicity (single exposure) Category 3
H280	Contains gas under pressure; may explode if heated
H290	May be corrosive to metals
H301	Toxic if swallowed
H314	Causes severe skin burns and eye damage
H317	May cause an allergic skin reaction

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Meitheal Pharmaceuticals, Inc.

Safety Data Sheet

SDS Title: Cytarabine Injection Safety Data Sheet	SDS Number: SDS-000004	Page Number: Page 10 of 10
Function: Regulatory Affairs	Effective Date: August 02, 2018	Version Number: 1.0

H318	Causes serious eye damage
H331	Toxic if inhaled
H335	May cause respiratory irritation
H361	Suspected of damaging fertility or the unborn child
H400	Very toxic to aquatic life
H402	Harmful to aquatic life

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.

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