



CYTARABINE INJECTION SAFETY DATA SHEET

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY

Product Identifier

Product name: Cytarabine Injection, 2 mg/ml (5 mL and 50 mL); 100 mg/ml (100 mL)

Intended Use of the Product

Pharmaceutical. Intravenous. Use only as directed. Refer to product insert for usage instructions and product information.

Name, Address, and Telephone of the Responsible Party

Supplier:

Mylan Institutional LLC
1718 Northrock Court
Rockford, IL 61103 USA
1-888-258-4199
www.mylan.com

Manufacturer:

Agila Specialities Pvt. Ltd.
A Mylan Company
Opposite IIM, Bilekahalli
Bangalore, India

Emergency Telephone Number

Emergency number : +1 877-446-3679

2. HAZARDS IDENTIFICATION

Patients/Consumers: Please refer to the product information insert or product label for appropriate consumer-specific information about this product when used according to the physician's directions. Pharmaceutical Agent – Handling of this product in its final form presents minimal occupational exposure risk.

Classification of the Substance or Mixture

Classification (GHS-US)

Skin Sens. 1 H317
Repr. 2 H361

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, spray.
P272 - Contaminated work clothing should not be allowed out of the workplace.
P280 - Wear protective clothing, protective gloves, eye protection.
P302+P352 - IF ON SKIN: Wash with plenty of soap and water.
P308+P313 - If exposed or concerned: Get medical advice/attention.
P321 - Specific treatment (see Section 4)
P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.
P362+P364 - Take off contaminated clothing and wash it before reuse.
P405 - Store locked up.
P501 - Dispose of contents/container according to local, regional, national, territorial, provincial, and international regulations.

Other Hazards Not available

Unknown acute toxicity (GHS-US) Not available

3. COMPOSITION/INFORMATION ON INGREDIENTS

Mixture

Name	Product identifier	% (w/w)	Classification (GHS-US)
Cytarabine	(CAS No) 147-94-4	2 - 10	Skin Sens. 1, H317 Repr. 2, H361

Additional Information: Sodium hydroxide and/or Hydrochloric acid are added to adjust pH.

Full text of H-phrases: see section 16

4. FIRST AID MEASURES

Description of 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).

Inhalation: The risk of inhalation exposure is negligible when product is in its final packaged form. If exposed and become symptomatic, move to fresh air and get medical attention if symptoms persist.

Skin Contact: Basic hygiene and appropriate precautions should prevent skin contact. If skin contact occurs, wash affected area with soap and water for at least 15 minutes. Should skin irritation, allergic reaction, or rash occur, remove contaminated clothing (if required) and seek medical advice.

Eye Contact: The risk of eye exposure is negligible when product is in its final packaged form. If eye contact occurs, flush immediately with water for at least 15 minutes. If easy to do, remove contact lenses. Get medical attention.

Ingestion: Ingestion is not an anticipated route of exposure. If accidental ingestion occurs, flush mouth out with water and get medical attention.

Most Important Symptoms and Effects Both Acute and Delayed

General: May cause an allergic skin reaction. Please refer to the package insert for more detailed information.

Inhalation: May cause respiratory irritation.

Skin Contact: May cause an allergic skin reaction.

Eye Contact: May cause eye irritation.

Ingestion: Ingestion is likely to be harmful or have adverse effects.

Injection: Very common adverse events include myelosuppression (neutropenia, thrombocytopenia and anemia), fever and chills, fatigue, weakness, infection, pneumonia, cough, nausea, vomiting and diarrhea, malaise, mucositis and anorexia.

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

Indication of Any Immediate Medical Attention and Special Treatment Needed

If exposed or concerned, get medical advice and attention. In the event of accidental injection, go immediately to the nearest emergency room.

5. FIREFIGHTING MEASURES

Extinguishing Media

Suitable extinguishing media: Not flammable. Use extinguishing media appropriate for surrounding fire.

Unsuitable extinguishing media: Do not use a heavy water stream. Use of heavy stream of water may spread fire.

Special Hazards Arising From the Substance or Mixture

Fire hazard: Not flammable.

Explosion hazard: Product is not explosive.

Reactivity: Hazardous reactions will not occur under normal conditions.

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: Carbon oxides (CO, CO₂). Nitrogen oxides.

Other information: Refer to Section 9 for flammability properties.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

General measures: Avoid all eye and skin contact and do not breathe vapor and mist.

For Non-Emergency Personnel

Protective equipment: Use appropriate personal protection equipment (PPE).

Emergency procedures: Evacuate unnecessary personnel.

For Emergency Personnel

Protective equipment: Equip cleanup crew with proper protection.

Environmental Precautions

Prevent entry to sewers and public waters.

Methods and Material for Containment and Cleaning Up

Methods for cleaning up: For small quantities associated with normal therapeutic use, collect spillage and transfer to a closed waste container for disposal. For large or bulk quantities, after absorption with inert material, collect spillage by sweeping up spilled material and place in a labeled, sealed container for proper disposal.

Reference to Other Sections

See heading 8, Exposure Controls and Personal Protection.

7. HANDLING AND STORAGE

Precautions for Safe Handling

Patients/Consumers: Patients should adhere to the instructions provided within the product information insert or product label for appropriate consumer-specific information about this product when used according to the physician's directions.

Hygiene measures: This SDS is for a pharmaceutical agent - Handling of this product in its final form presents minimal occupational exposure risk. In an occupational setting, handle in accordance with good industrial hygiene and safety procedures. Avoid contact with eyes, skin and clothing. Avoid breathing vapor or mist. Use appropriate personal protective equipment when handling and observe good personal hygiene measures after handling.

Conditions for Safe Storage, Including Any Incompatibilities

Storage conditions: Store in a dry, cool and well-ventilated place. Protect from heat and direct sunlight.

Special rules on packaging: Examine the vial for particulate matter and discoloration prior to administration. If the solution is discolored or contains solid particles (precipitate), do not use.

Specific End Use(s)

Pharmaceutical. Intravenous. Refer to product insert for usage instructions and product information.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control Parameters

No Occupational Exposure Limits (OELs) have been established for this product or its chemical components.

Exposure Controls

Appropriate engineering controls: Not generally required. Site-specific risk assessments should be conducted to determine the appropriate exposure control measures. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits.

Personal protective equipment: Gloves. The use of personal protective equipment may be necessary as conditions warrant.

Hand protection: Wear protective gloves made from PVC, neoprene, nitrile, vinyl, or PVC/NBR.

Eye protection: In laboratory, medical or industrial settings, or operations in which airborne particulates will be generated, safety glasses with side shields are recommended.

Skin and body protection: In laboratory, medical or industrial settings, impervious disposable gloves and protective clothing are recommended if skin contact with drug product is possible.

Respiratory protection: When manufacturing or handling product in large quantities and dusts or particulates may be generated, maintain airborne concentrations below recommended limits. Workplace risk assessments should be completed before specifying and implementing respirator usage. NIOSH/MSHA approved respirators for protection should be used if respirators are found to be necessary.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on Basic Physical and Chemical Properties

Physical state	: Liquid
Appearance	: Not available
Odor	: Not available
Odor threshold	: Not available
pH	: 7.7
Relative evaporation rate (butyl acetate=1)	: Not available
Melting/ Freezing point	: Not available
Boiling point	: Not available
Flash point	: Not available
Auto-ignition temperature	: Not available
Decomposition Temperature	: Not available
Flammability (solid, gas)	: Not available
Upper/Lower flammable limit	: Not available
Vapor pressure	: Not available
Relative vapor density at 20 °C	: Not available
Specific gravity	: Not available
Solubility	: Not available
Log Pow/Log Kow	: Not available
Viscosity	: Not available
Explosion data	: Not available

10. STABILITY AND REACTIVITY

Reactivity Hazardous reactions will not occur under normal conditions.
Chemical Stability Stable under normal conditions.
Possibility of Hazardous Reactions Hazardous polymerization will not occur.
Conditions to Avoid Direct sunlight. Extremely high or low temperatures.
Incompatible Materials Strong oxidizers. Strong bases. Strong acids.
Hazardous Decomposition Products Carbon oxides (CO, CO₂). Nitrogen oxides.

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects - Product

Acute toxicity: Not classified
LD50 and LC50 Data: Not available
Skin Corrosion/Irritation: Not classified
Serious Eye Damage/Irritation: Not classified
Respiratory or Skin Sensitization: May cause an allergic skin reaction.
Germ Cell Mutagenicity: Not classified
Teratogenicity: Not available
Carcinogenicity: Not classified
Specific Target Organ Toxicity (Repeated Exposure): Not classified
Reproductive Toxicity: Suspected of damaging fertility or the unborn child.
Specific Target Organ Toxicity (Single Exposure): Not classified
Aspiration Hazard: Not classified

Information on Toxicological Effects - Ingredient(s)

LD50 and LC50 Data: Not available

12. ECOLOGICAL INFORMATION

Toxicity Not classified
Persistence and Degradability Not available
Bioaccumulative Potential Not available

13. DISPOSAL CONSIDERATIONS

Waste disposal recommendations: Dispose of waste material in accordance with all local, regional, national, provincial, territorial and international regulations. Do not dispose of waste into sewer.
Additional information: Contaminated sharps should be discarded immediately or as soon as possible in containers that are closable, puncture-resistant, leak proof on sides and bottoms, and appropriately labeled. Contact your local health department for referral to a Safe Syringe Disposal Program.

14. TRANSPORT INFORMATION

In Accordance With ICAO/IATA/DOT/TDG
UN Number Not regulated for transport
UN Proper Shipping Name Not regulated for transport

15. REGULATORY INFORMATION

US Federal Regulations

Cytarabine Injection, 2 g/20 ml (100 mg/ml)	
SARA Section 311/312 Hazard Classes	Immediate (acute) health hazard Delayed (chronic) health hazard

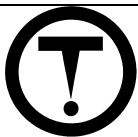
US State Regulations

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)	
RTK - U.S. - Massachusetts - Right To Know List	

Canadian Regulations

Cytarabine Injection, 2 g/20 ml (100 mg/ml)	
WHMIS Classification	Class D Division 2 Subdivision A - Very toxic material causing other toxic effects Class D Division 2 Subdivision B - Toxic material causing other toxic effects



This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations (CPR) and the SDS contains all of the information required by CPR.

16.	OTHER INFORMATION
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Revision date : 09/05/2014
Data sources : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200.
Other information : This document has been prepared in accordance with standards for workplace safety. The precautionary statements and warnings included might not apply in all cases. Your needs may vary depending on the potential for exposure in your workplace.

GHS Full Text Phrases:

Repr. 2	Reproductive toxicity Category 2
Skin Sens. 1	Skin sensitization Category 1
H317	May cause an allergic skin reaction
H361	Suspected of damaging fertility or the unborn child

Party Responsible For The Preparation Of This Document:

Mylan Global Environmental, Health, and Safety Department
Phone Number: 304-599-2595

This MSDS has been prepared for occupational exposure and intended to address some end-user concerns; however, patients/consumers are also strongly encouraged to review the product information insert or product label for consumer-specific information about this product. Patients/Consumers: Refer to the package insert or product label for appropriate consumer-specific information about this product when used according to manufacturer's directions.

To the best of our knowledge, the information contained herein is accurate. However, neither the above named supplier nor any of its subsidiaries assumes any liability whatsoever for completeness of the information herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

North America Mylan Pharmaceuticals