

SAFETY DATA SHEET

SECTION 1 : IDENTIFICATION

Product Name: Clofarabine Injection
Product Use/Restriction: Anticancer
Manufacturer Name: Alidac Pharmaceuticals Limited
Address: Plot No. 1A, PHARMEZ - Special Economic Zone
 Sarkhej-Bavla N.H. No. 8A, Village Matoda
 Tal. Sanand, Dist. Ahmedabad, Gujarat 382213
 India
General Phone Number: +91 2717 663 500
Emergency Phone Number: +91 2717 663 500
Distributor Name: Fresenius Kabi USA, LLC
Address: Three Corporate Drive
 Lake Zurich, Illinois 60047
General Phone Number: (847) 550-2300
Customer Service Phone Number: "(888) 386-1300"
Health Issues Information: (800) 551-7176
SDS Creation Date: February 08, 2017
SDS Revision Date: February 20, 2017

SECTION 2 : HAZARD(S) IDENTIFICATION

GHS Pictograms:



Signal Word: WARNING.

GHS Class: Reproductive toxicity, Category 2.
 Reproductive toxicity, Effects on or via lactation.

Hazard Statements: Suspected of damaging fertility or the unborn child.
 May cause harm to breast-fed children.

Precautionary Statements: Obtain special instructions before use.
 Do not handle until all safety precautions have been read and understood.
 Do not breathe dust/fume/gas/mist/vapours/spray.
 Avoid contact during pregnancy and while nursing.
 Wash hands thoroughly after handling.
 Do not eat, drink or smoke when using this product.
 Wear protective gloves/protective clothing/eye protection/face protection.
 IF exposed or concerned: Get medical advice/attention.
 Store locked up.
 Dispose of contents/container in accordance with Local, State, Federal and Provincial regulations.

Emergency Overview: This product is intended for therapeutic use only when prescribed by a physician. Potential adverse reactions from prescribed doses and overdoses are described in the package insert.

Route of Exposure: Inhalation Ingestion Eye contact Skin Absorption. Injection.

Potential Health Effects:

Eye: Contact with eyes may cause irritation.

SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS#	Ingredient Percent	EC Num.
Clofarabine	123318-82-1	1.0 mg	
Sodium chloride	7440-23-5	9.0 mg	231-132-9
Water for Injection	7732-18-5	- Quantity Sufficient. - to 1 ml	
Nitrogen	7727-37-9	- Quantity Sufficient.-	231-783-9

SECTION 4 : FIRST AID MEASURES

Eye Contact: Immediately flush eyes with plenty of water for at least 15 to 20 minutes. Ensure adequate flushing of the eyes by separating the eyelids with fingers. Get immediate medical attention.

Skin Contact:	Immediately wash skin with plenty of soap and water for 15 to 20 minutes, while removing contaminated clothing and shoes. Get medical attention if irritation develops or persists.
Inhalation:	If inhaled, remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Seek immediate medical attention.
Ingestion:	If conscious, flush mouth out with water immediately. Call a physician or poison control center immediately. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person.
Other First Aid:	For Adverse Event Information, please call (800) 551-7176.

SECTION 5 : FIRE FIGHTING MEASURES

Flash Point:	Not established.
Flash Point Method:	Not established.
Auto Ignition Temperature:	Not established.
Lower Flammable/Explosive Limit:	Not established.
Upper Flammable/Explosive Limit:	Not established.
Fire Fighting Instructions:	Evacuate area of unprotected personnel. Use cold water spray to cool fire exposed containers to minimize risk of rupture. Do not enter confined fire space without full protective gear. If possible, contain fire run-off water.
Extinguishing Media:	Use alcohol resistant foam, carbon dioxide, dry chemical, or water fog or spray when fighting fires involving this material. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Protective Equipment:	As in any fire, wear Self-Contained Breathing Apparatus (SCBA), MSHA/NIOSH (approved or equivalent) and full protective gear.
Hazardous Combustion Byproducts:	Thermal decomposition products may include smoke and toxic fumes. Oxides of carbon, oxides of nitrogen and other organic substances may be formed. Other undetermined low molecular weight hydrocarbon compounds may be released in small quantities depending upon specific conditions of combustion.

SECTION 6 : ACCIDENTAL RELEASE MEASURES

Personal Precautions:	Evacuate area and keep unnecessary and unprotected personnel from entering the spill area. Avoid personal contact and breathing vapors or mists. Use proper personal protective equipment as listed in Section 8.
Environmental Precautions:	Avoid runoff into storm sewers, ditches, and waterways.
Methods for containment:	Contain spills with an inert absorbent material such as soil, sand or oil dry.
Methods for cleanup:	Absorb spill with inert material (e.g., dry sand or earth), then place in a chemical waste container. After removal, flush spill area with soap and water to remove trace residue.

SECTION 7 : HANDLING and STORAGE

Handling:	When handling pharmaceutical products, avoid all contact and inhalation of vapor, mists and/or fumes. Use with adequate ventilation. Use only in accordance with directions.
Storage:	Store at 25°C (77°F); excursions permitted to 15 to 30°C (59 to 86°F).
Work Practices:	Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower.
Hygiene Practices:	Wash thoroughly after handling. Avoid contact with eyes and skin. Avoid inhaling vapor or mist.

SECTION 8: EXPOSURE CONTROLS, PERSONAL PROTECTION

Engineering Controls:	General ventilation is sufficient if this product is being used in a controlled medical setting (clinic, hospital, medical office) for its sole intended parenteral (injection) purpose. Otherwise, use appropriate engineering control such as process enclosures, local exhaust ventilation, or other engineering controls including use of a biosafety cabinet / fume hood to control airborne levels below recommended exposure limits.
Eye/Face Protection:	Chemical splash goggles. Wear a face shield also when splash hazard exist.
Skin Protection Description:	Protective laboratory coat, apron, or disposable garment recommended.
Hand Protection Description:	Wear appropriate protective gloves. Consult glove manufacturer's data for permeability data. Nitrile rubber or natural rubber gloves are recommended.
Respiratory Protection:	No personal respiratory protective equipment is normally required when this product is being used/administered by a licensed healthcare practitioner (i.e. an end-user such as a clinician / doctor / nurse) for its sole intended parenteral (injection) purpose in a controlled medical setting. The need for respiratory protection will vary according to the airborne concentrations and environmental conditions. A NIOSH approved air-purifying respirator with an organic vapor cartridge or canister may be permissible under certain circumstances. Consult the NIOSH web site (http://www.cdc.gov/niosh/npptl/topics/respirators/) for a list of respirator types and approved suppliers.
Other Protective:	Consult with local procedures for selection, training, inspection and maintenance of the personal protective equipment.

EXPOSURE GUIDELINES

Nitrogen :

Guideline ACGIH: TLV-STEL: Simple asphyxiant (D)

SECTION 9 : PHYSICAL and CHEMICAL PROPERTIES

Physical State:	Liquid solution.
Color:	White
Boiling Point:	Not established.
Melting Point:	216.51°C – 297.75°C
Solubility:	Soluble. in water.
Vapor Density:	Not established.
Vapor Pressure:	Not established.
Percent Volatile:	Not established.
pH:	4.5 - 7.5
Molecular Formula:	Mixture
Molecular Weight:	365.2
Flash Point:	Not established.
Flash Point Method:	Not established.
Auto Ignition Temperature:	Not established.

SECTION 10 : STABILITY and REACTIVITY

Chemical Stability:	Stable under normal temperatures and pressures.
Hazardous Polymerization:	Not reported.
Conditions to Avoid:	No conditions contributing to instability are known to exist for normal handling of this product.

SECTION 11 : TOXICOLOGICAL INFORMATION

Clofarabine :

Sensitization:	Not reported as a human skin sensitizer.
Mutagenicity:	Considered mutagenic in both non-reproductive cells (somatic cells) and reproductive cells (germ cells) of animals.
Reproductive Toxicity:	Considered to cause reproductive toxicity based on animal information.
Teratogenicity:	Considered to cause developmental toxicity in offsprings based on animal and human information.

SECTION 12 : ECOLOGICAL INFORMATION

Ecotoxicity:	No ecotoxicity data was found for the product.
Environmental Stability:	No environmental information found for this product.

SECTION 13 : DISPOSAL CONSIDERATIONS

Waste Disposal:	Dispose of in accordance with Local, State, Federal and Provincial regulations.
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SECTION 14 : TRANSPORT INFORMATION

DOT Shipping Name:	Not Regulated.
DOT UN Number:	Not Regulated.
IATA Shipping Name:	Not Regulated.
IATA UN Number:	Not Regulated.
Notes :	Not classified as Dangerous Goods. Not regulated per IATA and DOT regulations.

SECTION 15 : REGULATORY INFORMATION

Sodium chloride :

TSCA Inventory Status: Listed
Canada DSL: Listed
EC Number: 231-132-9
Nitrogen :
EC Number: 231-783-9

SECTION 16 : ADDITIONAL INFORMATION

HMIS Ratings:

HMIS Health Hazard: 3*
HMIS Fire Hazard: 0
HMIS Reactivity: 0
HMIS Personal Protection: X

SDS Creation Date: February 08, 2017
SDS Revision Date: February 20, 2017
SDS Revision Notes: Revision to Manufacturer's name, address, and telephone number.

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