

SAFETY DATA SHEET

SECTION 1 : IDENTIFICATION

Product Name: Decitabine for Injection
Manufacturer Name: Shilpa Medicare Limited
Address: Formulation Unit
 Plot No: S20 to S24A, Green Industrial Park, Polepally (V), Jadcherla (M),
 Mahaboobnagar Dist., Telangana, 509301
 India
General Phone Number: +91-08532 - 238704
General Fax Number: +91-08532 - 238876
Emergency Phone Number: +91-8532-235876
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: May 30, 2019
SDS Revision Date: October 14, 2019

SECTION 2 : HAZARD(S) IDENTIFICATION

GHS Pictograms:



Signal Word: DANGER!

GHS Class: Acute toxicity - Oral, Category 4
 Acute toxicity - Dermal, Category 4
 Acute toxicity - Inhalation, Category 4
 Skin irritation, Category 2
 Eye irritation, Category 2A
 Germ cell mutagenicity, Category 2
 Reproductive toxicity, Category 1B
 Specific target organ toxicity - single exposure, Category 3 (Respiratory system)

Hazard Statements: Harmful if inhaled. May cause respiratory irritation. Suspected of causing genetic defects. May damage fertility or the unborn child. Causes serious eye and skin irritation. Harmful if swallowed or if inhaled
 Harmful in contact with skin or if inhaled

Precautionary Statements: Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Wash hands thoroughly after handling. IF exposed or concerned: Get medical advice/attention. Store locked up. Wear protective gloves/protective clothing/eye protection/face protection. IF ON SKIN: Wash with plenty of soap and water. Avoid breathing dust/fume/gas/mist/vapours/spray. IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention. Store in a well-ventilated place. Keep container tightly closed. IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTER or doctor/physician if you feel unwell. Use only outdoors or in a well-ventilated area. Dispose of contents/container in accordance with Local, State, Federal and Provincial regulations. If skin irritation occurs: Get medical advice/attention. Take off contaminated clothing and wash it before reuse.

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.
Skin: May cause skin irritation.
Inhalation: May cause irritation of respiratory tract.
Ingestion: May cause irritation.

Signs/Symptoms: There is no known antidote for overdosage with decitabine for injection. Higher doses are associated with increased myelosuppression including prolonged neutropenia and thrombocytopenia. Standard supportive measures should be taken in the event of an overdose.

SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS#	Ingredient Percent	EC Num.
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Decitabine	2353-33-5	50 mg by weight	219-089-4
Potassium phosphate monobasic	7778-77-0	7.21 mg/g by weight	231-913-4
Sodium hydroxide	1310-73-2	1.23 mg/g by weight	215-185-5
Acetonitrile	75-05-8	29 (w/w) %	200-835-2

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 generates: Carbon oxides (CO, CO ₂). Hydrogen chloride. Chlorine oxides. Halogenated Compounds.

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 dust. Use proper personal protective equipment as listed in Section 8.
Environmental Precautions:	Avoid runoff into storm sewers, ditches, and waterways.
Methods for containment:	Contain materials by a method that controls dust generation.
Methods for cleanup:	Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

SECTION 7 : HANDLING and STORAGE

Handling:	Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. When handling pharmaceutical products, avoid all contact and inhalation of dust. 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). [See USP Controlled Room Temperature]. Keep container closed when not in use. Store in a dry, cool and well-ventilated place. Keep/Store away from direct sunlight, extremely high or low temperatures and incompatible materials. Containers which are opened should be properly resealed and kept upright to prevent leakage.
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 dust.

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

<u>Sodium hydroxide :</u>	
Guideline ACGIH:	TLV-TWA: 2 mg/m ³
<u>Acetonitrile :</u>	
Guideline ACGIH:	TLV-TWA: 20 ppm
Guideline NIOSH:	TLV-TWA: 20 ppm

SECTION 9 : PHYSICAL and CHEMICAL PROPERTIES

Physical State:	Crystalline powder.
Color:	White
Boiling Point:	Not established.
Melting Point:	Not established.
Solubility:	No data available.
Vapor Density:	Not established.
Vapor Pressure:	Not established.
Percent Volatile:	Not established.
pH:	3.5 - 6.5
Molecular Formula:	Mixture
Molecular Weight:	Variable.
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:	Direct sunlight, extremely high or low temperatures, and incompatible materials.
Incompatible Materials:	Strong acids, strong bases, strong oxidizers. Reducing agents. Water reactive materials.

SECTION 11 : TOXICOLOGICAL INFORMATION

Acute Toxicity:	Eye, skin, and respiratory irritation may occur.
Acute Effects:	Eye, skin, and respiratory irritation may occur.
Chronic Effects:	None known.
Reproductive Toxicity:	Presumed human reproductive toxicant
<u>Decitabine :</u>	
RTECS Number:	XZ3012000
Ingestion:	LD50-Oral-Rat 1290 mg/kg
<u>Potassium phosphate monobasic :</u>	
RTECS Number:	TC6615500
Skin:	LD50 Dermal - Rabbit - > 4,640 mg/kg

Inhalation:	LC50 Inhalation - Rat - male and female - 4 h - > 0.83 mg/l
Ingestion:	LD50 Oral - Rat - female - > 2,000 mg/kg
<u>Sodium hydroxide :</u>	
RTECS Number:	WB4900000
<u>Acetonitrile :</u>	
RTECS Number:	AL7700000
Skin:	LD50 Dermal - Rabbit - male and female - > 2,000 mg/kg
Inhalation:	LC50 Inhalation - Mouse - male and female - 4 h - 6.022 mg/l
Ingestion:	LD50 Oral - Mouse - male and female - 617 mg/kg

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:	Non regulated.
IATA UN Number:	Non regulated.
IMDG UN Number :	Non regulated.
IMDG Shipping Name :	Non regulated.

SECTION 15 : REGULATORY INFORMATION

<u>Decitabine :</u>	
EC Number:	219-089-4
<u>Potassium phosphate monobasic :</u>	
EC Number:	231-913-4
<u>Sodium hydroxide :</u>	
EC Number:	215-185-5
<u>Acetonitrile :</u>	
EC Number:	200-835-2

SECTION 16 : ADDITIONAL INFORMATION

HMIS Ratings:

HMIS Health Hazard:	1*
HMIS Fire Hazard:	1
HMIS Reactivity:	1
HMIS Personal Protection:	X

SDS Creation Date:	May 30, 2019
SDS Revision Date:	October 14, 2019
SDS Revision Notes:	"New formulation"

Disclaimer:	The information contained herein pertains to this material. It is the responsibility of each individual party to determine for themselves the proper means of handling and using these materials based on their purpose and intended use. Fresenius-Kabi assumes no liability resulting from the use of or reliance upon the information contained in this material safety data sheet. This material safety data sheet does not constitute the guaranty or specifications of the product.
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