SAFETY DATA SHEET

SECTION 1 : IDENTIFICATION

Product Name:	**Azacitidine for Injection**
Product Use/Restriction:	Antineoplastic.
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:	January 08, 2009
SDS Revision Date:	March 29, 2017

SECTION 2 : HAZARD(S) IDENTIFICATION

GHS Pictograms:

Signal Word: DANGER.

GHS Class:
Respiratory sensitisation. category 1.
Carcinogenicity. Category 1A.
Germ cell mutagenicity. Category 2.
Reproductive toxicity. Category 2.
Skin Irritation. Category 2.
Skin Sensitization. category 1.
Reproductive toxicity. Effects on or via lactation.

Hazard Statements:
May cause allergy or asthma symptoms or breathing difficulties if inhaled.
May cause cancer.
Suspected of causing genetic defects.
Suspected of damaging fertility or the unborn child.
Causes skin irritation.
May cause an allergic skin reaction.
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 breathing 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.
Contaminated work clothing should not be allowed out of the workplace.
Wear protective gloves/protective clothing/eye protection/face protection.
In case of inadequate ventilation wear respiratory protection.
IF ON SKIN: Wash with plenty of water.
IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
IF exposed or concerned: Get medical advice/attention.
Specific treatment (see ... on this label).
If skin irritation occurs: Get medical advice/attention.
If skin irritation or rash occurs: Get medical advice/attention.
If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.
Take off contaminated clothing and wash it before reuse.
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: May cause irritation to eyes, skin, and respiratory tract, nausea, vomiting, rash, diarrheah.

- Eye: Contact with eyes may cause irritation.
- Skin: May cause skin irritation.
- Inhalation: May cause irritation of respiratory tract.
- Ingestion: Harmful if swallowed.

Chronic Health Effects:
May cause fetal harm.
May cause blood abnormalities (neutropenia, thrombocytopenia, anemia).

	May impair fertility in men. Potentially carcinogenic and mutagenic
Signs/Symptoms:	The most commonly occurring adverse effects with therapeutic use include hematological toxicity (e.g.,thrombocytopenia, anemia, neutropenia), fever, gastrointestinal effects (e.g., nausea, vomiting, diarrhea, constipation), fatigue, injection site erythema, ecchymosis (skin discoloration caused by escape of blood into tissues from ruptured blood vessels).
Aggravation of Pre-Existing Conditions:	None specified

SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS#	Ingredient Percent	EC Num.
Azacitidine	320-67-2	50 by weight	
Mannitol	69-65-8	50 by weight	

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 controlled room temperature 20 to 25°C (68 to 77°F). [See USP Controlled Room Temperature].
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

Azacitidine :

Guideline ACGIH:	Not Established
Guideline OSHA:	Not Established

Mannitol :

Guideline ACGIH:	Not Established
Guideline OSHA:	Not Established

SECTION 9 : PHYSICAL and CHEMICAL PROPERTIES

Physical State:	Solid
Color:	White off-white
Odor:	No Data
Boiling Point:	225-230°C
Melting Point:	#ACTIOPHRASE_472#
Solubility:	slightly soluble.
Vapor Density:	Not established.
Vapor Pressure:	Not established.
Percent Volatile:	Not established.
pH:	Not available.
Molecular Formula:	C8H12N4O5
Molecular Weight:	244.2
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:	Protect from freezing.
Incompatible Materials:	Strong oxidizers and strong bases. acids
Special Decomposition Products:	Carbon oxides (CO, CO2). Nitrogen compounds

SECTION 11 : TOXICOLOGICAL INFORMATION

Acute Effects:	Eye, skin, and respiratory irritation may occur. May cause rash, vomiting, edema.

Azacitidine :

RTECS Number:	XZ3017500
Eye:	Administration onto the skin - Rabbit Rinsed with water.: 45 mg/24H

Skin:	Administration onto the skin - Rabbit Rinsed with water: 45 mg/24H Mild skin irritation was observed when a 9% solution of azacitidine was topically applied to rabbits.
Ingestion:	Oral - Mouse LD50: 572 mg/kg [Details of toxic effects not reported other than lethal dose value]
Chronic Effects:	May cause neutropeniaa and thrombocytopenia.
Carcinogenicity:	IARC: Group 2A: Probably carcinogenic to humans. NTP: Reasonably anticipated to be a human carcinogen.
Mutagenicity:	Mutagenic in bacterial and mamalian cell systems.
Reproductive Toxicity:	Possible decreased fertility in males.
Teratogenicity:	Teratogenic effects possible.
Other Toxicological Information:	Intravenous. - Mouse LD50: 229 mg/kg [Behavioral - ataxia Gastrointestinal - hypermotility, diarrhea Nutritional and Gross Metabolic - weight loss or decreased weight gain] Intravenous. - Mouse TDLo: 32500 ug/kg/5D (intermittent) [Behavioral - somnolence (general depressed activity) Behavioral - muscle contraction or spasticity Nutritional and Gross Metabolic - weight loss or decreased weight gain] Subcutaneous - Rat Mutation test systems : 25 mg/kg Intraperitoneal. - Mouse LD50: 68 mg/kg [Details of toxic effects not reported other than lethal dose value] Intraperitoneal. - Mouse TDLo: 100 mg/kg [Endocrine - changes in spleen weight Endocrine - changes in thymus weight Blood - changes in bone marrow (not otherwise specified)] Intraperitoneal. - Rat TDLo: 5 mg/kg [Reproductive - Fertility - post-implantation mortality (e.g. dead and/or resorbed implants per total number of implants)] Intraperitoneal. - Rat TDLo: 1 mg/kg [Reproductive - Effects on Embryo or Fetus - fetotoxicity (except death, e.g., stunted fetus) Reproductive - Effects on Embryo or Fetus - fetal death] Intraperitoneal. - Rat TDLo: 600 ug/kg [Reproductive - Effects on Embryo or Fetus - fetotoxicity (except death, e.g., stunted fetus) Reproductive - Specific Developmental Abnormalities - musculoskeletal system] Intraperitoneal. - Rat TDLo: 4 mg/kg [Reproductive - Effects on Newborn - live birth index (measured after birth) Reproductive - Effects on Newborn - growth statistics (e.g.%, reduced weight gain) Reproductive - Effects on Newborn - behavioral] Intraperitoneal. - Rat TDLo: 450 ug/kg [Reproductive - Specific Developmental Abnormalities - musculoskeletal system] Intraperitoneal. - Mouse TDLo: 5 mg/kg [Reproductive - Effects on Newborn - live birth index (measured after birth) Reproductive - Effects on Newborn - viability index (e.g., # alive at day 4 per # born alive)] Intraperitoneal. - Mouse TDLo: 500 ug/kg [Reproductive - Effects on Embryo or Fetus - fetotoxicity (except death, e.g., stunted fetus) Reproductive - Effects on Embryo or Fetus - fetal death] Intraperitoneal. - Mouse TDLo: 1 mg/kg [Reproductive - Effects on Embryo or Fetus - cytological changes (including somatic cell genetic material) Reproductive - Specific Developmental Abnormalities - Central Nervous System] Intraperitoneal. - Mouse TDLo: 2 mg/kg [Reproductive - Fertility - post-implantation mortality (e.g. dead and/or resorbed implants per total number of implants) Reproductive - Effects on Embryo or Fetus - fetotoxicity (except death, e.g., stunted fetus) Reproductive - Specific Developmental Abnormalities - Central Nervous System] Intraperitoneal. - Mouse TDLo: 2 mg/kg [Reproductive - Specific Developmental Abnormalities - craniofacial (including nose and tongue) Reproductive - Specific Developmental Abnormalities - musculoskeletal system Reproductive - Specific Developmental Abnormalities - other developmental abnormalities] Intraperitoneal. - Rat TDLo: 190 mg/kg/38W (intermittent) [Tumorigenic - equivocal tumorigenic agent by RTECS criteria Lungs, Thorax, or Respiration - tumors Reproductive - Tumorigenic effects - testicular tumors] Intraperitoneal. - Mouse TDLo: 100 mg/kg/50W (intermittent) [Tumorigenic - carcinogenic by RTECS criteria Blood - lymphoma, including Hodgkin's disease Skin and Appendages - tumors] Intraperitoneal. - Mouse TD: 284 mg/kg/43W (intermittent) [Tumorigenic - neoplastic by RTECS criteria Blood - lymphoma, including Hodgkin's disease] Intraperitoneal. - Mouse TD: 100 mg/kg/50W (intermittent) [Tumorigenic - neoplastic by RTECS criteria Lungs, Thorax, or Respiration - tumors] Intraperitoneal. - Mouse TD: 90 mg/kg/8W (intermittent) [Tumorigenic - neoplastic by RTECS criteria Lungs, Thorax, or Respiration - tumors] Intraperitoneal. - Mouse TD: 1 mg/kg [Tumorigenic - carcinogenic by RTECS criteria Blood - lymphoma, including Hodgkin's disease Reproductive - Tumorigenic effects - transplacental tumorigenesis] Intraperitoneal. - Rat Unscheduled DNA synthesis: 50 umol/kg Intraperitoneal. - Mouse Micronucleus test: 39 mg/kg Intraperitoneal. - Mouse Unscheduled DNA synthesis: 3 mg/kg Intraperitoneal. - Mouse DNA inhibition: 7143 ug/kg/3D (continuous) Intraperitoneal. - Mouse Mutation test systems : 7143 ug/kg/3D (continuous) Intraperitoneal. - Mouse Mutation test systems : 3 mg/kg Intraperitoneal. - Mouse Cytogenetic analysis: 3 mg/kg

Mannitol :

RTECS Number:	OP2060000
Ingestion:	Oral - Rat LD50: 13500 mg/kg [Details of toxic effects not reported other than lethal dose value] Oral - Mouse LD50: 22 gm/kg [Behavioral - Somnolence (general depressed activity); Gastrointestinal - Ulceration or bleeding from small intestine]
Other Toxicological Information:	Intravenous. - Rat LD50: 9690 mg/kg [Details of toxic effects not reported other than lethal dose value] Intravenous. - Mouse LD50: 7470 mg/kg [Details of toxic effects not reported other than lethal dose value] Intraperitoneal. - Mouse LD50: 14 gm/kg [Details of toxic effects not reported other than lethal dose value]

SECTION 12 : ECOLOGICAL INFORMATION

Ecotoxicity:	Expected to be presistent in the environment
Environmental Stability:	No environmental information found for this product.
Biodegradation:	Expected to have low biodegradation

SECTION 13 : DISPOSAL CONSIDERATIONS

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

SECTION 14 : TRANSPORT INFORMATION

DOT Shipping Name:	Not Regulated.
DOT UN Number:	Not Regulated.

SECTION 15 : REGULATORY INFORMATION

Azacitidine :

EINECS Number:	206-280-2
California PROP 65:	Listed: cancer.

Mannitol :

TSCA Inventory Status:	Listed
EINECS Number:	200-711-8
Canada DSL:	Listed

SECTION 16 : ADDITIONAL INFORMATION

HMIS Ratings:

HMIS Health Hazard:	3
HMIS Fire Hazard:	1
HMIS Reactivity:	1
HMIS Personal Protection:	X

SDS Creation Date:	January 08, 2009
SDS Revision Date:	March 29, 2017

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