(M)SDS Format : GHS

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FRESENIUS KABI

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SAFETY DATA SHEET

SECTION 1 : IDENTIFICATION

Product Name:	**Dacarbazine for Injection, USP**
Product Use/Restriction:	Antineoplastic.
Manufacturer 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:	June 10, 2015
(M)SDS Format:	GHS

SECTION 2 : HAZARD(S) IDENTIFICATION

GHS Pictograms:

Signal Word: DANGER.

GHS Class:
Serious Eye Damage. Category 1.
Skin corrosion. Category 1.
Respiratory sensitisation. Category 1.
Carcinogenicity. Category 2.
Reproductive toxicity. Category 2.
Skin Sensitization. Category 1.
Reproductive toxicity. Effects on or via lactation.

Hazard Statements:
Causes serious eye damage.
Causes severe skin burns and eye damage.
May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Suspected of causing cancer.
Suspected of damaging fertility or the unborn child.
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 SWALLOWED: Rinse mouth. Do not induce vomiting.
IF ON SKIN: Wash with plenty of water.
IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.
IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do.

Continue rinsing.
IF exposed or concerned: Get medical advice/attention.
Immediately call a POISON CENTER or doctor/physician.
Specific treatment (see ... on this label).
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.
Wash contaminated clothing 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. Avoid contact with skin, eyes, nostrils and mouth.

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

Potential Health Effects:

Eye: Contact with eyes may cause irritation.

Signs/Symptoms: Side effects from therapeutic doses include: hemopoietic depression hepatic toxicity, anaphylaxis, anorexia, nausea, and vomiting. Occupational exposure has not been fully investigated.

Aggravation of Pre-Existing Conditions: Individuals with previous hypersensitivity to dacarbazine, hemopoietic depression, and liver or kidney dysfunction.

SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS#	Ingredient Percent	EC Num.
Dacarbazine	4342-03-4	- %	
Mannitol	69-65-8	- %	
Citric Acid, Anhydrous	77-92-9	- %	

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

Personnel 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 refrigerated temperatures 2 to 8°C (36 to 46°F). Protect from light.
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

SECTION 9 : PHYSICAL and CHEMICAL PROPERTIES

Physical State:	Liquid solution.
Color:	White to pale yellow.
Boiling Point:	Not established.
Melting Point:	Not established.
Solubility:	Soluble. in water.
Vapor Density:	Not established.
Vapor Pressure:	Not established.
Percent Volatile:	Not established.

pH:	3.0-4.0 (reconstituted.)
Molecular Formula:	Mixture
Molecular Weight:	182.19
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 light.
Incompatible Materials:	Avoid contact with oxidizing agents.

SECTION 11 : TOXICOLOGICAL INFORMATION

Dacarbazine :

Acute Toxicity:

LD50: 567 mg/kg (IP Mouse)
LD50: 350 mg/kg (IP Rat)
LD50: 411 mg/kg (IV Rat)
LD50: 466 mg/kg (IV Mouse)

Dacarbazine :

IARC: IARC: Group 2B: Possibly carcinogenic to humans.

NTP: NTP: Reasonably anticipated to be a human carcinogen.

Teratogenicity: Pregnancy Category C: There are no adequate and well controlled studies in pregnant women. Dacarbazine should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Dacarbazine :

RTECS Number: NI3950000

Ingestion:
Oral - Rat LD50: 2147 mg/kg [Behavioral - Changes in motor activity (specific assay) Behavioral - Antipsychotic]
Oral - Mouse LD50: 2032 mg/kg [Behavioral - Changes in motor activity (specific assay) Behavioral - Antipsychotic]

Carcinogenicity: The carcinogenicity of dacarbazine was studied in rats and mice. Proliferative endocardial lesions, including fibrosarcomas and sarcomas were induced by dacarbazine in rats. In mice, administration of dacarbazine resulted in the induction of angiosarcomas of the spleen.

Other Toxicological Information:
Intravenous. - Human TDLo: 3500 ug/kg [Gastrointestinal - nausea or vomiting Blood - leukopenia Biochemical - Enzyme inhibition, induction, or change in blood or tissue levels - dehydrogenases]
Intravenous. - Rat LD50: 411 mg/kg [Behavioral - changes in motor activity (specific assay) Behavioral - antipsychotic]
Intravenous. - Mouse LD50: 466 mg/kg [Behavioral - changes in motor activity (specific assay) Behavioral - antipsychotic]
Intravenous. - Human TDLo: 93.75 mg/kg/12W (intermittent) [Behavioral - wakefulness Lungs, Thorax, or Respiration - dyspnea Gastrointestinal - decreased motility or constipation]
Intraperitoneal. - Rat LD50: 350 mg/kg [Details of toxic effects not reported other than lethal dose value]
Intraperitoneal. - Mouse LD50: 567 mg/kg [Details of toxic effects not reported other than lethal dose value]
Intraperitoneal. - Mouse TDLo: 1568 mg/kg/14D (intermittent) [Related to Chronic Data - death]
Intraperitoneal. - Rat DNA damage: 6 mg/kg
Intraperitoneal. - Rat DNA inhibition: 37500 ug/kg
Intraperitoneal. - Mouse Micronucleus test: 225 mg/kg/48H (intermittent)
Intraperitoneal. - Mouse Mutation test systems not otherwise specified: 9 mg/kg
Intraperitoneal. - Mouse Cytogenetic analysis: 9 mg/kg
Intraperitoneal. - Rat TDLo: 50 mg/kg [Reproductive - Effects on Embryo or Fetus - fetotoxicity (except death, e.g., stunted fetus)]
Intraperitoneal. - Rat TDLo: 200 mg/kg [Reproductive - Specific Developmental Abnormalities - urogenital system]
Intraperitoneal. - Rat TDLo: 100 mg/kg [Reproductive - Specific Developmental Abnormalities - musculoskeletal system]
Intraperitoneal. - Rat TDLo: 400 mg/kg [Reproductive - Specific Developmental Abnormalities - Central Nervous System Reproductive - Specific Developmental Abnormalities - craniofacial (including nose and tongue)]
Intraperitoneal. - Rat TDLo: 25 mg/kg [Tumorigenic - equivocal tumorigenic agent by RTECS criteria Reproductive - Tumorigenic effects - transplacental tumorigenesis Brain and Coverings - tumors]
Intraperitoneal. - Rat TDLo: 3900 mg/kg/26W (intermittent) [Tumorigenic - carcinogenic by RTECS criteria Blood - lymphoma, including Hodgkin's disease Skin and Appendages - tumors]
Intraperitoneal. - Mouse TDLo: 1950 mg/kg/26W (intermittent) [Tumorigenic - carcinogenic by RTECS criteria

Lungs, Thorax, or Respiration - tumors Blood - lymphoma, including Hodgkin's disease]

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]

Citric Acid, Anhydrous :

RTECS Number: GE7350000

Eye: Eye - Rabbit Standard Draize test.: 750 ug/24H [severe]

Skin: Administration onto the skin - Rabbit Standard Draize test.: 500 mg/24H [mild]

Ingestion: Oral - Rat LD50: 3 gm/kg [Details of toxic effects not reported other than lethal dose value]
Oral - Mouse LD50: 5040 mg/kg [Lungs, Thorax, or Respiration - Other changes Musculoskeletal - Other changes]
Oral - Mouse LD50: 7280 mg/kg [Details of toxic effects not reported other than lethal dose value]

Other Toxicological Information: Intravenous. - Mouse LD50: 42 mg/kg [Behavioral - convulsions or effect on seizure threshold Lungs, Thorax, or Respiration - cyanosis Gastrointestinal - changes in structure or function of salivary glands]
Intravenous. - Rabbit LD50: 330 mg/kg [Behavioral - convulsions or effect on seizure threshold Lungs, Thorax, or Respiration - cyanosis Gastrointestinal - changes in structure or function of salivary glands]
Subcutaneous - Rat LD50: 5500 mg/kg [Lungs, Thorax, or Respiration - other changes Musculoskeletal - other changes]
Subcutaneous - Mouse LD50: 2700 mg/kg [Lungs, Thorax, or Respiration - other changes Musculoskeletal - other changes]
Intraperitoneal. - Rat LD50: 290 mg/kg [Details of toxic effects not reported other than lethal dose value]
Intraperitoneal. - Mouse LD50: 903 mg/kg [Details of toxic effects not reported other than lethal dose value]
Intraperitoneal. - Rat LD16: 197 mg/kg [Details of toxic effects not reported other than lethal dose value]
Intraperitoneal. - Rat LD: 382 mg/kg [Details of toxic effects not reported other than lethal dose value]

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.

SECTION 14 : TRANSPORT INFORMATION

DOT Shipping Name: Not Regulated.

DOT UN Number: Not Regulated.

SECTION 15 : REGULATORY INFORMATION

Dacarbazine :

EINECS Number: 224-396-1

California PROP 65: Listed: developmental.

Mannitol :

TSCA Inventory Status: Listed

EINECS Number: 200-711-8

Canada DSL: Listed

Citric Acid, Anhydrous :

TSCA Inventory Status: Listed

EINECS Number:	201-069-1
Canada DSL:	Listed
Canada IDL:	Identified under the Canadian Hazardous Products Act Ingredient Disclosure List: 0.1%.409(80)

SECTION 16 : ADDITIONAL INFORMATION

HMIS Ratings:

SDS Creation Date:	January 08, 2009
SDS Revision Date:	June 10, 2015
SDS Format:	GHS
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