



## MATERIAL SAFETY DATA SHEET

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### SECTION 1 - PRODUCT & COMPANY IDENTIFICATION

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**1501 East Woodfield Road**                      **Emergency Telephone**                      **(800) 551-7176**  
**Suite 300 East**  
**Schaumburg, IL 60173**  
**(847) 969-2700**

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**Product Identifier:**                      Dacarbazine for Injection, USP  
**Chemical Name:**                      Dacarbazine  
**Category:**                      Antineoplastic

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### SECTION 2 - COMPOSITION

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<u>Ingredient</u>	<u>CAS Number</u>	<u>Amount</u>
Dacarbazine	4342-03-4	100 mg and 200 mg vials
Citric Acid, Anhydrous	77-92-9	Proprietary
Mannitol	69-65-8	Proprietary

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### SECTION 3 - HAZARDS IDENTIFICATION

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**Route of Entry:**                      Inhalation, eye/skin contact, or ingestion

**Chemical Listing as Carcinogen**

**NTP:**                      Yes - Category 2 Anticipated Human Carcinogen

**IARC:**                      Yes - Group 2B Possible Human Carcinogen

**OSHA:**                      No

**Note:**                      There is limited but increasing evidence that personnel involved in the preparation and administration of parenteral antineoplastics may be at some risk due to potential mutagenicity, teratogenicity, and/or carcinogenicity of these agents. The actual risk is not known. The US Pharmacopeia advisory panels recommends the cautious handling in both preparation and disposal of antineoplastic agents. Precautions that have been suggested include: use of a biological containment cabinet during reconstitution and dilution of parenteral medications, use of disposable surgical gloves and masks, use of proper technique to prevent contamination of medication onto the work area and operator, and proper disposal of needles, syringes, vials, and ampules.

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## SECTION 4 - EMERGENCY & FIRST AID MEASURES

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<b>Eyes:</b>	Immediately flush eyes with water for at least 15 minutes. Seek medical attention.
<b>Skin:</b>	Remove contaminated clothing immediately. Flush area with water for at least 15 minutes. Wash exposed area with soap and water. Seek medical attention if pain, redness, or swelling persists.
<b>Inhalation:</b>	Move exposed subject to fresh air immediately. Give artificial respiration and cardiopulmonary resuscitation (CPR) if required. Seek medical attention.
<b>Ingestion:</b>	Flush mouth with water and seek medical attention immediately. If individual is conscious, induce vomiting. Never induce vomiting on an unconscious individual.
<b>Contact Info:</b>	For Adverse Event Information, please call (800) 551-7176 or (847) 969-2700.

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## SECTION 5 - FIRE FIGHTING MEASURES

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### Fire and Explosion Data

<b>Closed Cup Flash Point:</b>	NE
<b>Open Cup Flash Point:</b>	NE
<b>Fire Point:</b>	NE
<b>Autoignition:</b>	NE
<b>Lower Explosion Limit:</b>	NE
<b>Upper Explosion Limit:</b>	NE
<b>General Hazard:</b>	When heated to decomposition, toxic fumes may be emitted.
<b>Fire Fighting Instructions:</b>	Water spray or multi-purpose ABC extinguisher.
<b>Fire Fighting Equipment:</b>	Wear self-containing breathing apparatus and protective clothing.
<b>Hazardous Combustion Products:</b>	Decomposition products may include potentially hazardous byproducts of nitrogen oxides, carbon monoxide, and sulfur dioxide.

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## SECTION 6 - ACCIDENTAL RELEASE MEASURES

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<b>Clean-Up:</b>	Wear recommended personal protective equipment (See Section 8 - Exposure Controls/Personal Protection). Use absorbent towels or brooms to clean-up spill. Wipe surface area clean with soap and water.
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## SECTION 7 - HANDLING AND STORAGE

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**General Handling:** When handling pharmaceutical products, avoid all contact and inhalation of dust, fumes, mist, and/or vapors associated with the product.

**Storage Conditions:** Store in a refrigerator 2°-8°C (36°-46°F). Protect from light.

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## SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION

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**Engineering Controls:** Class II Type B Biological safety cabinet or other well-ventilated area recommended. Restrict handling to authorized personnel.

### Personal Protective Equipment

**Eye Protection:** Safety glasses or goggles recommended.

**Hand Protection:** Disposable latex or nitrile gloves recommended.

**Respiratory Protection:** With satisfactory ventilation, respiratory protection is usually not required.

**Skin Protection:** Disposable garments or lab coat if direct skin contact is anticipated.

### Exposure Limits:

<u>Compound</u>	<u>Issuer</u>	<u>Type</u>	<u>OEL</u>
Dacarbazine	OSHA	PEL	NE
	ACGIH	TLV	NE
	---	STEL	NE
Citric Acid, Anhydrous	OSHA	PEL	NE
	ACGIH	TLV	NE
	---	STEL	NE
Mannitol	OSHA	PEL	NE
	ACGIH	TLV	NE
	---	STEL	NE

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## SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

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**Physical Form/Appearance:** White to pale yellow colored solid

**Boiling Point/Boiling Range:** NA

**Melting Point/Melting Range:** NA

**Freezing Point:** NA

**Vapor Pressure :** NA

**Relative Vapor Density:** NA

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**SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES...continued**

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**Percent Volatiles:** NA  
**pH:** 3.0-4.0 (reconstituted)  
**Molecular Weight:** 182.19  
**Solvent Solubility:** Soluble in water  
**Note:** NA

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**SECTION 10 - STABILITY AND REACTIVITY**

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**Stability:** Stable  
**Conditions to Avoid:** Avoid contact with oxidizers and exposure to light.  
**Hazardous Polymerization:** Does not occur.

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**SECTION 11 - TOXICOLOGY INFORMATION**

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

**Medical Conditions Aggravated by Accidental Exposure:** Individuals with previous hypersensitivity to dacarbazine, hemopoietic depression, and liver or kidney dysfunction.

**Acute Toxicity:**

<u>Compound</u>	<u>Type</u>	<u>Route</u>	<u>Species</u>	<u>Dosage</u>
Dacarbazine	LD <sub>50</sub>	Oral	Rat	2147 mg/kg
	LD <sub>50</sub>	Oral	Mouse	2032 mg/kg
	LD <sub>50</sub>	IP	Mouse	567 mg/kg
	LD <sub>50</sub>	IP	Rat	350 mg/kg
	LD <sub>50</sub>	IV	Rat	411 mg/kg
	LD <sub>50</sub>	IV	Mouse	466 mg/kg

**Other:** 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.

**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.

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**SECTION 12 - TRANSPORTATION INFORMATION**

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**UN/NA Number:** NA  
**U.S. DOT Hazard Class:** NA  
**Proper Shipping Name:** NA  
**Shipping Label:** NA

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**SECTION 13 - DISPOSAL INFORMATION**

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**Disposal Procedure :** Treatment, storage, transportation, and disposal must be in accordance with applicable federal, state, and local regulations.

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**SECTION 14 - OTHER**

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**Key to Abbreviations:** ACGIH - American Conference of Governmental Industrial Hygienists  
HEPA - High Efficiency Particulate Air  
IARC - International Agency for Research on Cancer  
NA - Not Applicable  
NE - Not Established  
NG - Not Given  
NIOSH - National Institute for Occupational Safety and Health  
NTP - National Toxicology Program  
OEL - Occupational Exposure Limit  
OSHA - Occupational Safety and Health Administration  
PEL - Permissible Exposure Limit  
PPM - Parts Per Million  
QS - Quantity Sufficient  
RCRA - Resource Conservation and Recovery Act  
STEL - Short Term Exposure Limit  
TLV - Threshold Limit Value  
USP - United States Pharmacopeia

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