

## SAFETY DATA SHEET

**Product Name: Dacarbazine for Injection, USP**

### 1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

<b>Manufacturer Name And Address</b>	Hospira, Inc. 275 North Field Drive Lake Forest, Illinois 60045 USA	Hospira Australia Pty Ltd 1 Lexia Place Mulgrave VIC 3170 AUSTRALIA
<b>Emergency Telephone #'s</b>	CHEMTREC: North America: 800-424-9300; International 1-703-527-3887; Australia - 61-290372994; UK - 44-870-8200418	
<b>Hospira, Inc., Non-Emergency</b>	224 212-2000	
<b>Product Name</b>	Dacarbazine for Injection, USP	
<b>Synonyms</b>	5-(3,3-dimethyl-1-triazeno)-imidazole-4-carboxamide; DTIC.	

### 2. HAZARD(S) IDENTIFICATION

**Emergency Overview** Dacarbazine for Injection, USP, is a powder containing dacarbazine, an anti-neoplastic drug that acts as an alkylating agent after metabolic activation by the liver. Dacarbazine is used to treat some types of cancers. It is a cytotoxic agent, and should be considered potentially irritating to the eyes and respiratory tract, a potential occupational reproductive hazard, and a potential human carcinogen. Based on clinical use, possible target organs may include the bone marrow, gastrointestinal tract, central nervous system, liver, and skin.

#### U.S. OSHA GHS Classification

<b>Physical Hazards</b>	<b>Hazard Class</b>	<b>Hazard Category</b>
	Not Classified	Not Classified

<b>Health Hazards</b>	<b>Hazard Class</b>	<b>Hazard Category</b>
	Eye Damage/Irritation	2B
	Skin Corrosion/Irritation	2
	Toxic to Reproduction	2
	Germ Cell Mutagenicity	2
	Carcinogenicity	2
	STOT - RE	2

#### **Label Element(s)**

**Pictogram**



**Signal Word**

Warning

**Hazard Statement(s)**

Causes eye irritation  
 Causes skin irritation  
 Suspected of damaging fertility or the unborn child  
 Suspected of causing genetic defects  
 Suspected of causing cancer  
 May cause damage to organs through prolonged or repeated exposures

**2. HAZARD(S) IDENTIFICATION: continued**

**Precautionary Statement(s)**

<b>Prevention</b>	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Wear protective gloves/protective clothing/eye protection/face protection. Do not breathe vapors/spray. Wash hands thoroughly after handling.
<b>Response</b>	If exposed or concerned: Get medical advice/attention. Get medical attention if you feel unwell.  IF ON SKIN: Wash with plenty of water. If skin irritation occurs: Get medical advice/attention. Take off contaminated clothing and wash it before reuse.  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 attention.

**3. COMPOSITION/INFORMATION ON INGREDIENTS**

<b>Active Ingredient Name</b>	Dacarbazine	Citric Acid Monohydrate
<b>Chemical Formula</b>	C <sub>6</sub> H <sub>10</sub> N <sub>6</sub> O	C <sub>6</sub> H <sub>8</sub> O <sub>7</sub> • H <sub>2</sub> O

Component	Approximate Percent by Weight	CAS Number	RTECS Number
Dacarbazine	40-44	4342-03-4	NI3950000
Citric Acid Monohydrate	42-44	5949-29-1	GE7810000

Non-hazardous ingredients present at greater than 1% include mannitol.

**4. FIRST AID MEASURES**

<b>Eye Contact</b>	Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.
<b>Skin Contact</b>	Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.
<b>Inhalation</b>	Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.
<b>Ingestion</b>	Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

**5. FIRE FIGHTING MEASURES**

<b>Flammability</b>	None anticipated for this product. However, many organic powders will combust at elevated temperatures.
<b>Fire &amp; Explosion Hazard</b>	None anticipated for this product. Avoid the creation of dusty environments.
<b>Extinguishing Media</b>	As with any fire, use extinguishing media appropriate for primary cause of fire such as carbon dioxide, dry chemical extinguishing powder or foam.
<b>Special Fire Fighting Procedures</b>	No special provisions required beyond normal firefighting equipment such as flame and chemical resistant clothing and self contained breathing apparatus.

## 6. ACCIDENTAL RELEASE MEASURES

**Spill Cleanup and Disposal** For spilled powder, isolate area around spill. Put on suitable protective clothing and equipment as specified by site spill control procedures. Collect the spilled powder using techniques that minimize powder migration. Clean affected area with soap and water. Dispose of materials according to the applicable federal, state, or local regulations.

If a spill occurs after reconstitution, absorb liquid with suitable material and clean affected area with soap and water. Dispose of materials according to the applicable federal, state, or local regulations.

## 7. HANDLING AND STORAGE

**Handling** Dacarbazine is a cytotoxic agent. Appropriate procedures should be implemented during the handling and disposal of cytotoxic antineoplastics agents to minimize potential exposures. Several guidelines on handling cytotoxic antineoplastic agents have been published. There is no general agreement that all of the procedures recommended in the guidelines are necessary or appropriate. Consult your hygienist or safety professional for your site requirements.

Avoid ingestion, inhalation, skin contact, and eye contact. When handling the powder, precautions may include the use of a containment cabinet during the weighing, reconstitution and/or solubilization of this antineoplastic agent. The use of disposable gloves and respiratory protection is recommended. Proper disposal of contaminated vials, syringes, or other materials is required when working with this product.

**Storage** No special storage is required for hazard control. However, employees should be trained on the proper storage procedures for antineoplastic agents. For product protection, follow storage recommendations noted on the product case label, the primary container label, or the product insert.

**Special Precautions** No special precautions required for hazard control. Persons with known hypersensitivities to dacarbazine, women who are pregnant, or women who want to become pregnant, should consult a health and/or safety professional prior to handling open containers of this product.

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Exposure Guidelines

Component	Exposure Limits			
	OSHA-PEL	ACGIH-TLV	AIHA WEEL	Hospira EEL
Dacarbazine	8-hr TWA: Not Established	8-hr TWA: Not Established	8-hr TWA: Not Established	8-hr TWA: Not Established
Citric Acid Monohydrate	8-hr TWA: Not Established	8-hr TWA: Not Established	8-hr TWA: Not Established	8-hr TWA: Not Established

Notes: OSHA PEL: US Occupational Safety and Health Administration – Permissible Exposure Limit  
 ACGIH TLV: American Conference of Governmental Industrial Hygienists – Threshold Limit Value.  
 AIHA WEEL: Workplace Environmental Exposure Level  
 EEL: Employee Exposure Limit.  
 TWA: 8-hour Time Weighted Average.

**8. EXPOSURE CONTROLS/PERSONAL PROTECTION: continued**

<b>Respiratory Protection</b>	Respiratory protection is normally not needed during intended product use. However, if the generation of dusts or aerosols is likely, and engineering controls are not considered adequate to control potential airborne exposures, the use of an approved air-purifying respirator with a HEPA cartridge (N99 or equivalent) is recommended under conditions where airborne dust or aerosol concentrations are not expected to be excessive. For uncontrolled release events, or if exposure levels are not known, provide respirators that offer a high protection factor such as a powered air purifying respirator or supplied air. A respiratory protection program that meets OSHA's 29 CFR 1910.134 and ANSI Z88.2 requirements must be followed whenever workplace conditions require respirator use. Personnel who wear respirators should be fit tested and approved for respirator use as required.
<b>Skin Protection</b>	When handling this product, disposable gloves should be worn at all times. Further, the use of double gloves is recommended. Disposable gloves made from nitrile, neoprene, polyurethane or natural latex generally have low permeability to many antineoplastic agents. Persons known to be allergic to latex rubber should select a non-latex glove. Gloves should be changed regularly, and removed immediately after known contamination. Care should be taken to minimize inadvertent contamination when removing and/or disposing of gloves.
<b>Eye Protection</b>	As a minimum, the use of chemical safety goggles is recommended when handling this product.
<b>Engineering Controls</b>	When handling the dry powder, local exhaust ventilation is recommended to minimize employee exposure. The use of an enclosure, such as an approved ventilated cabinet designed to minimize airborne exposures, is recommended.

**9. PHYSICAL/CHEMICAL PROPERTIES**

<b>Appearance/Physical State</b>	An ivory colored solid
<b>Odor</b>	Odorless
<b>Odor Threshold</b>	NA
<b>pH</b>	3-4 for a 1% solution when reconstituted
<b>Melting point/Freezing Point</b>	205°C
<b>Initial Boiling Point/Boiling Point Range</b>	NA
<b>Flash Point</b>	NA
<b>Evaporation Rate</b>	NA
<b>Flammability (solid, gas)</b>	NA
<b>Upper/Lower Flammability or Explosive Limits</b>	NA
<b>Vapor Pressure</b>	NA
<b>Vapor Density (Air =1)</b>	NA
<b>Relative Density</b>	NA
<b>Solubility</b>	Slightly soluble in water and alcohol
<b>Partition Coefficient: n-octanol/water</b>	NA
<b>Auto-ignition Temperature</b>	NA
<b>Decomposition Temperature</b>	NA
<b>Viscosity</b>	NA

**10. STABILITY AND REACTIVITY**

<b>Reactivity</b>	Not determined.
<b>Chemical Stability</b>	Stable under standard use and storage conditions. Dacarbazine is sensitive to light and heat; elevated temperatures may cause a color change from ivory to pink which is indicative of some decomposition.
<b>Hazardous Reactions</b>	Not determined
<b>Conditions to Avoid</b>	Not determined
<b>Incompatibilities</b>	Not determined
<b>Hazardous Decomposition Products</b>	Not determined. During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides (COx) and nitrogen oxides (NOx).
<b>Hazardous Polymerization</b>	Not anticipated to occur with this product.

**11. TOXICOLOGICAL INFORMATION**

**Acute Toxicity** - Not determined for the product formulation. Information for the ingredients is as follows:

<b>Ingredient(s)</b>	<b>Percent</b>	<b>Test Type</b>	<b>Route of Administration</b>	<b>Value</b>	<b>Units</b>	<b>Species</b>
Dacarbazine	100	LD50	Oral	2147	mg/kg	Rat
Dacarbazine	100	LD50	Oral	2032	mg/kg	Mouse
Dacarbazine	100	LD50	Intravenous	411	mg/kg	Rat
Dacarbazine	100	LD50	Intravenous	466	mg/kg	Mouse
Dacarbazine	100	LD50	Intraperitoneal	350	mg/kg	Rat
Dacarbazine	100	LD50	Intraperitoneal	567	mg/kg	Mouse
Citric Acid Monohydrate	100	LD50	Intraperitoneal	375	mg/kg	Rat

LD50 is the dosage producing 50% mortality.

<b>Occupational Exposure Potential</b>	There are scientific studies that suggest that personnel (e.g. nurses, pharmacists, etc.) who prepare and administer parenteral antineoplastics (e.g. in hospitals) may be at some risk due to potential mutagenicity, teratogenicity, and/or carcinogenicity of these materials if workplace exposures are not properly controlled. The actual risk in the workplace is not known.
<b>Signs and Symptoms</b>	None anticipated from normal handling of this product. This product should be considered irritating to the skin, eyes, and respiratory tract. In clinical use, adverse effects have included anorexia, severe nausea and vomiting, bone marrow depression, diarrhea, skin reactions, alopecia, abnormal ECG, hypotension, a flu-like syndrome, facial flushing and paraesthesia, headache, polyneuropathy, blurred vision, and seizures.
<b>Aspiration Hazard</b>	None anticipated from normal handling of this product.
<b>Dermal Irritation/Corrosion</b>	None anticipated from normal handling of this product. However, inadvertent skin contact with this product may produce irritation and redness.
<b>Ocular Irritation/Corrosion</b>	None anticipated from normal handling of this product. However, inadvertent eye contact with this product may produce irritation, with redness and tearing.
<b>Dermal or Respiratory Sensitization</b>	None anticipated from normal handling of this product. In clinical use, erythematous and urticarial rashes have been observed infrequently. Rarely, photosensitivity reactions have occurred.

**11. TOXICOLOGICAL INFORMATION: continued**

<b>Reproductive Effects</b>	None anticipated from normal handling of this product. Administration of dacarbazine to male rats at dosages up to 50 mg/kg twice/week for nine weeks had no effect on fertility. Administration of dacarbazine to female rats for two weeks prior to mating at dosages up to 30 mg/kg/day had no adverse effects on fertility. Administration of a single dosage of 800 or 1,000 mg/kg dacarbazine to pregnant rats on day 11 or 12 of gestation produced skeletal reduction defects, some cleft palates, and encephaloceles. Similarly, intraperitoneal administration of dacarbazine to pregnant rats throughout organogenesis produced an increase in resorptions, a decrease in litter size, and an increase in skeletal anomalies at doses from 30 mg/kg/day and higher. Major malformations in the rat offspring were increased at maternal doses of 50 and 70 mg/kg/day. In pregnant rabbits, maternal doses of 10 mg/kg/day produced abortion and an increase in major malformations. The no-observed-adverse-effect dosage was 5 mg/kg/day in the study in rabbits.
<b>Mutagenicity</b>	Dacarbazine was positive in the Ames test for mutagenicity. Dacarbazine was also positive for genotoxicity in vitro in rodent cell assays.
<b>Carcinogenicity</b>	Oral or intraperitoneal administration of dacarbazine to rats produced tumors in the mammary glands, thymus, spleen and brain.
<b>Carcinogen Lists</b>	<b>IARC:</b> Group 2B <b>NTP:</b> Suspect Human Carcinogen <b>OSHA:</b> Not listed
<b>Specific Target Organ Toxicity – Single Exposure</b>	NA
<b>Specific Target Organ Toxicity – Repeat Exposure</b>	Based on clinical use, possible target organs may include the bone marrow, gastrointestinal tract, central nervous system, liver, skin, and the fetus.

**12. ECOLOGICAL INFORMATION**

<b>Aquatic Toxicity</b>	Not determined for product.  Citric Acid LC50 (96 hrs, static) = 1516 - 2600 mg/L in freshwater fish EC50(72 hrs) ≈ 120 mg/L in Daphnia magna EC3 (7 days) = 640 mg/L in algae
<b>Persistence/Biodegradability</b>	Not determined for product.  Citric acid is considered readily biodegradable. Approximately 98% was degraded after 48 hours (OECD Guideline 302B, domestic, non-adapted sewage).
<b>Bioaccumulation</b>	Not determined for product.
<b>Mobility in Soil</b>	Not determined for product.

**13. DISPOSAL CONSIDERATIONS**

<b>Waste Disposal</b>	All waste materials must be properly characterized. Further, disposal should be performed in accordance with the federal, state or local regulatory requirements.
<b>Container Handling and Disposal</b>	Dispose of container and unused contents in accordance with federal, state and local regulations.

### 14. TRANSPORTATION INFORMATION

<b>ADR/ADG/ DOT STATUS</b>	Not regulated
<b>Proper Shipping Name</b>	NA
<b>Hazard Class</b>	NA
<b>UN Number</b>	NA
<b>Packing Group</b>	NA
<b>Reportable Quantity</b>	NA
<b>ICAO/IATA STATUS</b>	Not regulated
<b>Proper Shipping Name</b>	NA
<b>Hazard Class</b>	NA
<b>UN Number</b>	NA
<b>Packing Group</b>	NA
<b>Reportable Quantity</b>	NA
<b>IMDG STATUS</b>	Not regulated
<b>Proper Shipping Name</b>	NA
<b>Hazard Class</b>	NA
<b>UN Number</b>	NA
<b>Packing Group</b>	NA
<b>Reportable Quantity</b>	NA

Notes: DOT - US Department of Transportation Regulations

### 15. REGULATORY INFORMATION

<b>US TSCA Status</b>	Exempt.
<b>US CERCLA Status</b>	Not listed
<b>US SARA 302 Status</b>	Not listed
<b>US SARA 313 Status</b>	Not listed
<b>US RCRA Status</b>	Not listed
<b>US PROP 65 (Calif.)</b>	This product is, or contains chemical(s) known to the State of California to cause developmental toxicity. This product is or contains chemical(s) known to the State of California to cause cancer.

Notes: TSCA, Toxic Substance Control Act; CERCLA, US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act; SARA, Superfund Amendments and Reauthorization Act; RCRA, US EPA, Resource Conservation and Recovery Act; Prop 65, California Proposition 65

**GHS/CLP Classification\***      \*In the EU, classification under GHS/CLP does not apply to certain substances and mixtures, such as medicinal products as defined in Directive 2001/83/EC, which are in the finished state, intended for the final user.

<b>Hazard Class</b>	<b>Hazard Category</b>	<b>Pictogram</b>	<b>Signal Word</b>	<b>Hazard Statement</b>
NA	NA	NA	NA	NA
<b>Prevention</b>	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Wear protective gloves/protective clothing/eye protection/face protection. Do not breathe vapors/spray. Wash hands thoroughly after handling.			
<b>Response</b>	If exposed or concerned: Get medical advice/attention. Get medical attention if you feel unwell.  IF ON SKIN: Wash with plenty of water. If skin irritation occurs: Get medical advice/attention. Take off contaminated clothing and wash it before reuse.  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 attention.			

**15. REGULATORY INFORMATION: continued**

<b><u>EU Classification*</u></b>	*Medicinal products are exempt from the requirements of the EU Dangerous Preparations Directive.
<b>Classification(s)</b>	NA
<b>Symbol</b>	NA
<b>Indication of Danger</b>	NA
<b>Risk Phrases</b>	NA
<b>Safety Phrases</b>	S23: Do not breathe vapor/spray S24: Avoid contact with the skin S25: Avoid contact with eyes S37/39 Wear suitable gloves and eye/face protection.

**16. OTHER INFORMATION**

Notes: NA

ACGIH TLV	American Conference of Governmental Industrial Hygienists – Threshold Limit Value
CAS	Chemical Abstracts Service Number
CERCLA	US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act
DOT	US Department of Transportation Regulations
EEL	Employee Exposure Limit
IATA	International Air Transport Association
LD <sub>50</sub>	Dosage producing 50% mortality
NA	Not applicable/Not available
NE	Not established
NIOSH	National Institute for Occupational Safety and Health
OSHA PEL	US Occupational Safety and Health Administration – Permissible Exposure Limit
Prop 65	California Proposition 65
RCRA	US EPA, Resource Conservation and Recovery Act
RTECS	Registry of Toxic Effects of Chemical Substances
SARA	Superfund Amendments and Reauthorization Act
STEL	15-minute Short Term Exposure Limit
STOT - SE	Specific Target Organ Toxicity – Single Exposure
STOT - RE	Specific Target Organ Toxicity – Repeated Exposure
TSCA	Toxic Substance Control Act
TWA	8-hour Time Weighted Average

MSDS Coordinator: Hospira GEHS  
 Date Prepared: October 17, 2012  
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