



300 Northfield Road
 Bedford, OH 44146
 Telephone: (800) 562-4797
 -or- (440) 232-3320

MATERIAL SAFETY DATA SHEET

Section I - IDENTITY

Common/Trade Name: Dacarbazine for Injection (200 mg)
Chemical Names: 5-(3,3-dimethyl-1-triazeno)-imidazole-4-carboxamide
Synonyms: DTIC-Dome, Biocarbazine R, Deticene, NCI-C04717, NSC-45388
Manufacturer's Name: BEN VENUE LABORATORIES, INC.
Address: 300 NORTHFIELD ROAD
 BEDFORD, OH 44146
Emergency Telephone Number: Chemtrec: 1(800)424-9300
Telephone Number for Info.: (440)232-3320 or (800)562-4797
Medical Emergency: Professional Services 1(800)521-5169
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Section II - HAZARDOUS INGREDIENTS/COMPOSITION INFORMATION

<u>Component</u>	<u>%</u>	<u>CAS#</u>	<u>OSHA PEL</u>	<u>ACGIH TLV</u>	<u>Other Limits Recommended</u>
Dacarbazine	42%	4342-03-4	NONE	NONE	NONE
Mannitol	16%	87-78-5	NONE	NONE	NONE
Citric Acid Monohydrate	42%	77-92-9	NONE	NONE	NONE

Dacarbazine is a sterile parenteral injectable drug presented as a powder cake. It must be reconstituted with Sterile Water for Injection prior to administration.

Section III - HEALTH HAZARD DATA

Routes of Entry: Product may be absorbed via inhalation, ingestion, or skin contact.
Health Hazard (Acute & Chronic): Dacarbazine is a cytotoxic, anticancer agent used for treating metastatic malignant melanoma. Dacarbazine can produce a variety of health effects to the respiratory, blood-forming, digestive and reproductive systems. These affects have been seen in patients receiving Dacarbazine in therapeutic treatment. Dacarbazine may cause irritation to the eyes, skin and respiratory tract. It is a carcinogen, mutagen and teratogen.
Carcinogenicity: NTP? YES Category 2 – Classified as an anticipated Human Carcinogen
 IARC Monographs? Yes, Group 2B – Classified as a Possible Human Carcinogen
 OSHA Regulated? NO
Signs & Symptoms of Exposure: May cause nausea, vomiting, decreased appetite, diarrhea, rash, muscle/joint aches, decreased white/red cells, hair loss and liver damage.

Medical Conditions Generally Aggravated by Exposure: Persons with sensitivity to Dacarbazine or those who have conditions with depressed white and/or red blood cells. Also individuals with liver or kidney conditions.

BVL Hazard Category: 4

Section IV - FIRST AID MEASURES

Eye Exposure: Flush eyes with large volumes of water for 15 or more minutes.

Skin Exposure: Wash skin with cool, soapy water.

Ingestion: If ingestion occurs, flush mouth with water and seek medical attention immediately. If person is conscious, induce vomiting; never induce vomiting on an unconscious person.

Inhalation: If difficulty breathing, administer oxygen. Seek attention of a physician immediately. Physician to monitor blood count and liver count, post-exposure.

Section V - FIRE AND EXPLOSION HAZARD DATA

Flash Point (Method Used): Not Applicable **LEL:** NA **UEL:** NA

Flammable Limits: Not Applicable

Extinguishing Media: Use water or a multi-purpose ABC extinguisher.

Special Fire Fighting Procedures: As with all fires, evacuate personnel to a safe area. Fire fighters must wear self-contained breathing apparatus to avoid inhalation of smoke. Product is not expected to present a fire hazard concern.

Unusual Fire/Explosion Hazards: NONE

Section VI - ACCIDENTAL RELEASE INFORMATION

Release to Land: Wet Dacarbazine with water to prevent dusting and absorb with proper sorbents. Prevent contact with sewers and waterways.

Release to Air: If dust is generated, reduce exposures by ventilating and prevent the generation of dust. Wear respiratory protection.

Release to Water: Refer to local water authority; drain disposal is not recommended. Refer to local, state, and federal guidelines.

Section VII - PRECAUTIONS FOR SAFE HANDLING AND USE

Steps to be taken in case material is released or spilled: See Section VI above.

Wear all necessary protective equipment including nitrile or latex gloves, protective clothing, safety glasses, and air-purifying respirator with HEPA (P100) cartridges. Large spills require the use of SCBA.

Waste Disposal Method: Dispose of via incineration at an approved, permitted facility.

Do not drain dispose. Follow Federal, State and Local regulations for waste disposal.

Precautions to be taken in handling and storing: Store under refrigeration at 2-8°C (36-46°F).

Other Precautions: Follow OSHA guidelines on the safe handling of cytotoxic products (see Section XVI). Protect product from light.

Section VIII - CONTROL MEASURES AND PERSONAL PROTECTIVE EQUIPMENT

Respiratory Protection: Under normal use, respirators are not required. If dust generation is likely, an air-purifying respirator with HEPA cartridge (P100) must be worn. For large spill emergencies, SCBA may be required. Personnel wearing respirators should be fit tested and approved for respirator use under the OSHA Respiratory Protection Standard, 29 CFR 1910.134.

Ventilation: Use with adequate ventilation such as in a Class II Type B biological safety cabinet.

Protective Gloves: Nitrile or latex

Eye Protection: Safety glasses or goggles

Other Protective Clothing or Equipment: Lab coat

Work/Hygienic Practices: Wash hands following use. No eating, drinking, or smoking when handling this product.

Section IX - PHYSICAL/CHEMICAL CHARACTERISTICS

Physical State:	Solid	Specific Gravity:	Not Applicable
Appearance and Odor:	Off-White Powder with no odor	Melting Point:	Not Available
Boiling Point:	Not Applicable	Evaporation Rate:	Not Applicable
Vapor Pressure:	Not Applicable	Solubility in Water:	Soluble in Water
Vapor Density:	Not Applicable	pH:	3-4 when reconstituted with water

Section X - STABILITY AND REACTIVITY DATA

Stability: Stable **Conditions to Avoid:** Avoid contact with oxidizers.

Incompatibility (Materials to Avoid): Oxidizers

Hazardous Decomposition or Byproducts: Decomposition products of this compound may include potentially hazardous byproducts of nitrogen oxides, carbon monoxide and sulfur dioxide.

Hazardous Polymerization: Will not occur.

Section XI - TOXICOLOGICAL INFORMATION

For active ingredient Dacarbazine: RTECS # HE1150000

LD₅₀ oral, rat = 2147 mg/kg

LD₅₀ oral, mouse = 2032 mg/kg

LD₅₀ intraperitoneal, mouse = 567 mg/kg

LD₅₀ intraperitoneal, rat = 350 mg/kg

LD₅₀ intravenous, rat = 411 mg/kg

LD₅₀ intravenous, mouse = 466 mg/kg

Other toxicity data is available in the Registry of Toxic Effects of Chemical Substances (RTECS)

Carcinogenicity: The Carcinogenicity of Dacarbazine was studied in rats and mice. Dacarbazine induced proliferative endocardial lesions, including fibrosarcomas and sarcomas in rats. In mice, administration of Dacarbazine resulted in the induction of angiosarcomas of the spleen.

Developmental Toxicity: Dacarbazine has been shown to be teratogenic in rats when given in doses 20 times the human daily dose on day 12 of gestation. In rabbits, Dacarbazine daily dose seven times the human daily dose given on days 6-15 of gestation resulted in fetal skeletal anomalies. Additional reproductive health and toxicity data is available from the National Institute for Occupational Safety and Health (NIOSH) Registry of Toxic Effects of Chemical Substances (RTECS).

Section XII - ENVIRONMENTAL IMPACT INFORMATION

Information is currently not available on the environmental impact of Dacarbazine. Handle in a manner that prevents spills or releases to the environment.

Section XIII - DISPOSAL INFORMATION

Dispose of via incineration at a permitted, licensed facility, according to local, state, and federal guidelines.

Section XIV - TRANSPORTATION INFORMATION

Dacarbazine is not a DOT Hazardous material according to 49 CFR 172.101
Dacarbazine is not a Marine Pollutant.

Section XV - REGULATORY INFORMATION

SARA 313 listed?: NO
CERCLA listed? NO
RCRA listed?: NO
California Proposition 65 Code: CD
Florida Toxic Substance: Listed as a toxic substance by the state of Florida
Massachusetts Hazardous Substance Codes: 1,3 *E*C*
Pennsylvania Hazardous Substance Code: S
Minnesota Hazardous Substance: Codes: RT Carcinogen?: YES

Section XVI - OTHER DATA

1. Hospital personnel preparing or administering toxic parenteral agents should wear disposable latex gloves, safety glasses, a closed-front gown with cuffs, and respiratory protection. Preparation of all toxic or potent agents should be done in a Class II laminar flow hood or biological safety cabinet with exhaust air discharged external to the room environment. All needles, syringes, vials, and other equipment or disposable clothing that have contacted this agent should be segregated for incineration.
2. Persons administering this drug to patients must be careful to avoid needle sticks to syringes and other sharps used in the administration. All needle sticks must be reported to your company management.
3. Use of this product should be through or under the direction of a physician. This MSDS does not address therapeutic use of this material.
4. BVL Hazard Category Definitions (internal hazard ranking used by Ben Venue Laboratories):
1 = Low Toxicity
2 = Moderate Toxicity
3 = Potent or Toxic
4 = Highly Potent or Toxic
5 = Extremely Potent or Toxic
5. OEL=Occupational Exposure Limit. An internal limit set by Ben Venue Laboratories for the

recommended limit of employee exposure to airborne dusts or aerosols that should not be exceeded over an eight-hour time-weighted average.

6. Dacarbazine is considered a Hazardous Drug as described in the NIOSH Alert: Preventing Occupational Exposures to Antineoplastic and Other Hazardous Drugs in Health Care Settings. Employees who prepare or administer hazardous drugs or who work in areas where these drugs are used should follow specific handling guidelines in order to prevent exposure to these agents in the air or on work surfaces, clothing, or equipment.

7. **The Following Guidance Information is excerpted from the NIOSH Alert:**

Elements of a Hazardous Drug Handling Program include:

- Establishment and implementation of written policies and protocols to ensure the safe handling of oncolytic and/or potent drugs, including receipt of product.
- Training and education of employees on the recognition, evaluation and control of Hazardous Drugs
- Effective Planning and design of the workplace
- Use of best practice control measures and specialized equipment such as ventilated cabinets or isolators designed for worker protection
- Wearing recommended personal protective equipment
- An integrated health surveillance program that: includes the assessment and counseling of prospective employees before they commence any work involving oncolytic and/or potent drugs and related waste

8. **Published guidance on the handling and transport of cytotoxic drugs:**

NIOSH Alert – Preventing occupational exposures to antineoplastic and other hazardous drugs in health care settings

<http://www.cdc.gov/niosh/docs/2004-165/>

National Study Commission on Cytotoxic Exposure: Recommendation for handling Cytotoxic Agents:

<http://www.nih.gov/od/ors/ds/pubs/cyto/index.htm>

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