

MATERIAL SAFETY DATA SHEET

Prepared to U.S. OSHA, CMA, ANSI and Canadian WHMIS Standards

PART I *What is the material and what do I need to know in an emergency?*

1. PRODUCT IDENTIFICATION

PRODUCT NAME (AS LABELED): **DACARBAZINE FOR INJECTION**
PRODUCT USE: Medical treatment of metastatic malignant melanoma and Hodgkin's Disease.

SUPPLIER/MANUFACTURER'S NAME: **GensiaSicor Pharmaceuticals, Inc.**
ADDRESS: 17 Hughes
 Irvine, CA 92618

CHEMTREC EMERGENCY NO.: 1-800-424-9300 (United States)**
 1-202-483-7616 (International Collect)

BUSINESS PHONE: 1-800-729-9991
FAX: 1-949-855-8210

Common Names: DTIC; DTIC-Dome⁷

Chemical Name: For Active Ingredient: 5-(3,3-DIMETHYL-1-TRIAZENYL)-1H-IMIDAZOLE-4-CARBOXAMIDE

Chemical Formula: For Active Ingredient: C₆H₁₀N₆O

Chemical Family: Imidazole

How Supplied: 100 or 200 mg in vials.

2. COMPOSITION and INFORMATION ON INGREDIENTS

CHEMICAL NAME	CAS #	% by weight	EXPOSURE LIMITS IN AIR					
			ACGIH		OSHA			OTHER
			TLV mg/m ³	STEL mg/m ³	PEL mg/m ³	STEL mg/m ³	IDLH mg/m ³	
Dacarbazine The following exposure limits are for A Particulates, Not Otherwise Specified.	4342-03-4	40-45	DACARBAZINE IS A CYTOTOXIC AGENT. IT IS ALSO A POSSIBLE HUMAN CARCINOGEN. ALL WORK PRACTICES MUST BE DESIGNED TO REDUCE HUMAN EXPOSURE TO THE LOWEST LEVEL.					
Citric Acid, Anhydrous	77-92-9	40-45	NE	NE	NE	NE	NE	NE
Mannitol	69-65-8	10-20	NE	NE	NE	NE	NE	NE

NE = Not Established See Section 16 for definition of terms used. Mppcf: Millions of Particles Per Cubic Foot

NOTE: ALL WHMIS required information is included in appropriate sections based on the ANSI Z400.1-1993 format.

**Chemtrec Number: Use only in the event of a chemical emergency involving a spill, leak, fire, exposure or accident involving this chemical.

3. HAZARD IDENTIFICATION

EMERGENCY OVERVIEW: This is an off-white, odorless powder. The primary health hazard associated with over-exposure to this product during an emergency response situation would be irritation of contaminated skin or eyes. Dacarbazine is a possible human carcinogen. This product must be substantially pre-heated before ignition can occur. Dacarbazine is not normally reactive. Emergency responders must wear adequate personal protective equipment for the situation to which they are responding.

SYMPTOMS OF OVER-EXPOSURE BY ROUTE OF EXPOSURE:

Dacarbazine is generally intended for intravenous injection under the supervision of physicians experienced in cancer chemotherapy. Dose-dependant adverse effects that occur with therapeutic treatments associated with this product include anorexia, nausea, vomiting, fever, muscle pain, malaise, and adverse effects on the blood system, pulmonary toxicity, skin changes, and mucous membrane changes. Anaphylactic reactions, consisting of hypotension, fever, chills, mental confusion, and wheezing, are also reported.

This material is a powerful cytotoxic agent. The extent of entry into the body by most routes has not been fully investigated. Occupational over-exposures to this product may cause severe acute or chronic effects in humans, as described in the following paragraphs.

INHALATION: Inhalation of Dacarbazine powder can cause mild to moderate irritation of the nose and throat. Symptoms of such over-exposure may include coughing, sneezing, and dry nose. Because of the small size of individual containers (100-200 mg vial), inhalation of significant amounts of the product is not anticipated to occur.

CONTACT WITH SKIN or EYES: Contact of the product with the skin may cause reddening, pain, and irritation. Contact of the product with the eyes can cause severe irritation and tissue damage. Prolonged eye contact may result in blindness. Citric Acid, a component of this product, is a potential allergen; prolonged or repeated skin contact can lead to rashes, dermatitis, and the development of other allergy-like symptoms.

SKIN ABSORPTION: Skin absorption is not reported to be a significant route of over-exposure to the components of this product.

INGESTION: Though not anticipated to be a significant route of occupational exposure, ingestion of this product may cause gastrointestinal distress, nausea, vomiting, and diarrhea. Symptoms similar to those listed for "Injection" may occur. Ingestion of significant quantities of this product may be fatal.

INJECTION: Local redness and pain are the primary symptoms of accidental injection, in terms of anticipated occupational over-exposure effect. There are variety of adverse reactions associated with therapeutic use of this product. Though medical personnel are not anticipated to experience over-exposures to therapeutic doses of this product, the following information is presented to provide medical personnel additional information on potential health effects.

The most common adverse reactions associated with injection of Dacarbazine are as follows:

- X Hemopoietic depression (reduction in number of leucocytes, platelets)
- X Anemia; possible fatal leukopenia, thrombocypenia
- X Liver damage
- X Anaphylaxis
- X Anorexia, nausea, vomiting, fever, muscle pain, malaise, hair loss
- X Rashes, photosensitivity reactions

HAZARDOUS MATERIAL INFORMATION SYSTEM			
HEALTH		(BLUE)	3 3
FLAMMABILITY		(RED)	1
REACTIVITY		(YELLOW)	0
PROTECTIVE EQUIPMENT			X
EYES	RESPIRATORY	HANDS	BODY
See Section 8 of this MSDS.			
PPE used during medical treatment of cancer.			

3. HAZARD IDENTIFICATION (Continued)

HEALTH EFFECTS OR RISKS FROM EXPOSURE (An explanation in lay terms).

ACUTE: The primary health effects which may be experienced by medical personnel over-exposed to this product are irritation of contaminated skin and eyes, or pain, redness and local swelling after accidental injection. In the event of over-exposures via injection to therapeutic doses of this product, fever, chest pain, burning at the site of injection, and a variety of other health effects may occur. Additionally, this product may cause allergic-type reactions in sensitive individuals. Death may occur in the event of an accidental over-dose.

CHRONIC: Hemopoietic depression (reduction in number of leucocytes, platelets) and anemia may be associated with chronic exposure to this product. Refer to Section 11 (Toxicological Information) for additional information on this product.

PART II *What should I do if a hazardous situation occurs?*

4. FIRST-AID MEASURES

SKIN EXPOSURE: If the product contaminates the skin, immediately begin decontamination with running water. Remove exposed or contaminated clothing, taking care not to contaminate eyes. The minimum recommended flushing time is 15 minutes.

EYE EXPOSURE: If this product contaminates the eyes, open victim's eyes while under gently running water. Use sufficient force to open eyelids. While flushing with water, have victim "roll" eyes. Minimum flushing is for 15 minutes.

INHALATION: If dusts or particulates of this product are inhaled, remove victim to fresh air. If necessary, use artificial respiration to support vital functions. Remove or cover gross contamination to avoid exposure to rescuers.

INGESTION: If the product is swallowed, CALL PHYSICIAN OR POISON CONTROL CENTER FOR MOST CURRENT INFORMATION. If professional advice is not available, DO NOT induce vomiting. Victim should drink milk, egg whites, or large quantities of water. Never induce vomiting or give diluents (milk or water) to someone who is unconscious, having convulsions, or who cannot swallow.

Victims must seek immediate medical attention, especially if an adverse reaction occurs. Rescuers should be taken for medical attention, if necessary. Take copy of label and MSDS to physician or health professional with victim.

5. FIRE-FIGHTING MEASURES

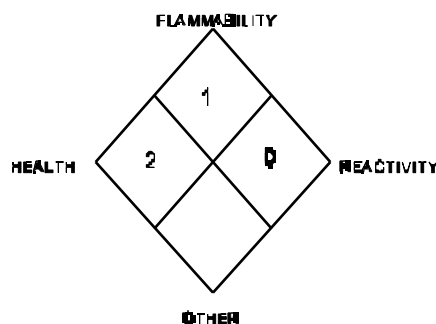
FLASH POINT, EC (method): Not flammable.

AUTOIGNITION TEMPERATURE, EC: Not applicable.

FLAMMABLE LIMITS (in air by volume, %): Lower: Not applicable.
Upper: Not applicable.

FIRE EXTINGUISHING EQUIPMENT:

Water Spray: OK Carbon Dioxide: OK Foam: OK
Dry Chemical: OK Halon: OK Other: Any "ABC"
Class



UNUSUAL FIRE and EXPLOSION HAZARDS: This product must be substantially pre-heated before ignition can occur. At extremely high temperatures, this product will decompose to produce irritating vapors and toxic gases (i.e. carbon monoxide, carbon dioxide, nitrogen oxides). This product may decompose explosively above 250EC (482EF).

Explosion Sensitivity to Mechanical Impact: Not sensitive.

Explosion Sensitivity to Static Discharge: Not sensitive.

SPECIAL FIRE-FIGHTING PROCEDURES: Incipient fire responders should wear eye protection. Structural fire fighters must wear Self-Contained Breathing Apparatus (SCBA) and full protective equipment. If protective equipment is contaminated by this product, it should be thoroughly washed with running water, prior to removal of SCBA respiratory protection. Fire-fighters whose protective equipment becomes contaminated should thoroughly shower with warm, soapy water and should receive medical evaluation.

6. ACCIDENTAL RELEASE MEASURES

SPILL and LEAK RESPONSE: For small releases of this product (200 mg) wear double latex or nitrile gloves, full body gown, and safety glasses. Large or uncontrolled releases should be responded to by trained personnel using pre-planned procedures. Proper protective equipment should be used, including double latex or nitrile gloves, full body gown, and full-face respirator equipped with a High Efficiency Particulate (HEPA) filter. Self-Contained Breathing Apparatus (SCBA) can be used instead of the air-purifying respirator.

In case of a spill, clear the affected area, protect people, and respond with trained personnel. Clean-up spilled solid with a damp sponge, polypad, or other appropriate materials. Avoid generating dust of this product. Decontaminate the area of the spill thoroughly by using detergent and water. Place all spill residue in an appropriate container. Dispose of in accordance with Federal, State, and local waste disposal regulations.

PART III

How can I prevent hazardous situations from occurring?

7. HANDLING and STORAGE

WORK PRACTICES and HYGIENE PRACTICES: DACARBAZINE IS A CYTOTOXIC AGENT. ALL WORK PRACTICES MUST BE DESIGNED TO REDUCE HUMAN EXPOSURE TO THE LOWEST LEVEL. As with all chemicals, avoid getting this material ON YOU or IN YOU. Do not eat or drink while handling the product. Wash hands thoroughly after handling this product or equipment and containers which contain this product. Follow SPECIFIC USE INSTRUCTIONS supplied with product.

Particular care in working with this product must be practiced in pharmacies and other preparation areas, during manufacture of this product, and during patient administration. Operations of high risk associated with the use of this product include:

- ! Withdrawal of needles from drug vials;
- ! Drug transfers using syringes and needles or filter straws;
- ! Opening ampules; and,
- ! Expulsion of air from drug-filled syringes.

DO NOT CLIP OR CRUSH NEEDLE WITH WHICH THIS PRODUCT WAS IN CONTACT. Use of this product should meet the following provisions.

- ! Work should be performed in a designated area for working with hazardous drugs;
- ! Containment devices, such as a Biological Safety Cabinet, should be used;
- ! Contaminated waste must be properly handled; and,
- ! Work areas must be regularly decontaminated.

STORAGE and HANDLING PRACTICES: Employees must be trained to properly use the product. Ensure vials are properly labeled. Store the product away from incompatible materials. Refrigerate product in original container at 2-8 EC (36-46 EF). Protect from light.

PROTECTIVE PRACTICES DURING MAINTENANCE OF CONTAMINATED EQUIPMENT: When cleaning non-disposable equipment, wear latex or nitrile gloves (double-gloving is recommended), goggles, and lab coat. Wash equipment with soap and water. All needles, syringes, vials, and other disposable items contaminated with this product should be disposed of properly. Prevent dispersion of particulates by wetting or dampening surfaces prior to clean-up of equipment.

8. EXPOSURE CONTROLS - PERSONAL PROTECTION

VENTILATION and ENGINEERING CONTROLS: Use with adequate ventilation. Follow standard medical product handling procedures. Admixtures or manipulations of this drug should be carried out in a cytotoxic drug safety cabinet.

The cabinet should be regularly cleaned following the manufacturer's recommendations, but no less frequently than weekly. All surfaces should be thoroughly washed with water and detergent and triple rinsed. During decontamination, workers should wear the same equipment recommended in Section 6 (Accidental Release Measures) of this MSDS for the clean-up of a large spill. HEPA filters on the cytotoxic drug safety cabinet should be changed every six months.

Technicians should be aware of the risks associated with this drug via training, and should use the same equipment recommended in Section 6 (Accidental Release Measures) of this MSDS for the clean-up of large spills. The safety cabinet should be tested and certified as recommended by the National Sanitation Foundation in Standard Number

8. EXPOSURE CONTROLS - PERSONAL PROTECTION (Continued)

RESPIRATORY PROTECTION: A full-face respirator with a HEPA filter should be used until a Biological Safety Cabinet is installed. A respirator is not required for routine conditions of use with a Biological Safety Cabinet.

EYE PROTECTION: Chemical splash goggles, or regular splash goggles, with a full face-shield.

HAND PROTECTION: Double glove, using latex, nitrile, or rubber gloves. Check gloves for leaks. Wash hands before putting on gloves and after removing gloves. Gloves should cover the gown cuff.

BODY PROTECTION: A full body gown which is closed at the front and has long sleeves. The gown should be made of Tyvek^(TM), PE-Coated Tyvek^(TM), or SARANEX^(TM).

Product Preparation Instructions for Medical Personnel: Handle this material following standard medical practices and following the recommendations presented on the Package Insert.

HMS Personal Protective Equipment Rating: X - Special consideration in equipment selection is required.

9. PHYSICAL and CHEMICAL PROPERTIES

RELATIVE VAPOR DENSITY (Air = 1): Not applicable.

EVAPORATION RATE (n-BuAc=1): > 1

SPECIFIC GRAVITY: Not determined.

MELTING/FREEZING POINT: Decomposes 250 EC (482 EF)

SOLUBILITY IN WATER: Slightly Soluble.

BOILING POINT: Not applicable.

VAPOR PRESSURE, mm Hg @ 25 EC: Not applicable.

pH: Not applicable.

ODOR THRESHOLD: Not applicable.

COEFFICIENT OF OIL/WATER DISTRIBUTION (Partition Coefficient): Not applicable.

APPEARANCE and COLOR: This is an off-white, odorless powder.

HOW TO DETECT THIS SUBSTANCE (warning properties): The appearance of this product may act as a distinguishing characteristic of this product.

10. STABILITY and REACTIVITY

STABILITY: This product is stable when stored under refrigerated conditions up to the shelf-life of the product. Dacarbazine, a component of this product, is stable in neutral solutions in the absence of light.

MATERIALS WITH WHICH SUBSTANCE IS INCOMPATIBLE: This material is generally compatible with other common materials in a medical facility. This solution would not be compatible with strong oxidizers, strong acids, and strong bases.

HAZARDOUS POLYMERIZATION: Will not occur.

CONDITIONS TO AVOID: Heat may cause product to decompose, destroying the product and producing irritating vapors and toxic gases (i.e. oxides of carbon and nitrogen). Protect vials of this product from light. Avoid contact with incompatible chemicals.

PART IV

Is there any other useful information about this material?

11. TOXICOLOGICAL INFORMATION

TOXICITY DATA: The following data are available for the product and its components.

DACARBAZINE:

Microsomal Mutagenicity Assay- *Salmonella typhimurium* 100 µg/plate
Sister Chromatid Exchange-Hamster; ovary 200 mg/L

Intraperitoneal-Rat TDLo: 50 mg/kg (12D preg):
Teratogenic effects
Oral-Rat TDLo: 1730 mg/kg/15 Weeks, Continuous:
Carcinogenic effects

DACARBAZINE (Continued):

Intraperitoneal-Rat TDLo: 25 mg/kg (20D preg):
Equivocal tumorigenic agent, Teratogenic effects
Intraperitoneal-Rat TDLo: 3900 mg/kg/ 26 Weeks,
Intermittent: Carcinogenic effects

Intraperitoneal-Mouse TDLo: 1950 mg/kg/ 26 Weeks, Intermittent: Carcinogenic effects
Oral-Rat TD: 3700 mg/kg/14 Weeks, Continuous: Carcinogenic effects

DACARBAZINE (Continued):
Intravenous-Human TDLo: 3500 µg/kg:
Gastrointestinal tract effects, Blood effects
Oral-Rat LD₅₀: 2147 mg/kg
Intraperitoneal-Rat LD₅₀: 350 mg/kg
Intravenous-Rat LD₅₀: 411 mg/kg
Oral-Mouse LD₅₀: 2032 mg/kg
Intraperitoneal-Mouse LD₅₀: 567 mg/kg
Parenteral-Hamster LD₁₀: 250 mg/kg

11. TOXICOLOGICAL INFORMATION (Continued)

TOXICITY DATA (Continued):

CITRIC ACID:

Skin Irritancy (rabbit): 500 mg/ 24 hours; moderate

Eye Irritancy (rabbit): 750 µg/ 24 hours; severe

LD₅₀ (oral, rat): 3 g/kg

LD₅₀ (Intraperitoneal, rat): 883 mg/kg

CITRIC ACID (Continued)

LD₅₀ (intraperitoneal, mouse): 903 mg/kg

LD₅₀ (subcutaneous, mouse): 2700 mg/kg

LD₅₀ (intravenous, mouse): 42 mg/kg

LD₅₀ (subcutaneous, rat): 5500 mg/kg

LD₅₀ (oral, mouse): 5040 mg/kg

LCLO (oral, rabbit) : 7000 mg/kg

LD₅₀ (intravenous, rabbit): 330 mg/kg

MANNITOL:

oms-other microorganisms 1 mol/L

DNA Inhibition-Human: lymphocyte 50 mmol/L

Intravenous-Man TDLo: 17,143 mg/kg/2 days, continuous: Cardiovascular effects, Gastrointestinal tract effects, Kidney effects

Oral-Rat LD₅₀: 13,500 mg/kg

Intravenous-Rat LD₅₀: 9690 mg/kg

Oral-Mouse LD₅₀: 22 g/kg

Intraperitoneal-Mouse LD₅₀: 14 g/kg

Intravenous-Mouse LD₅₀: 7470 mg/kg

SUSPECTED CANCER AGENT: Components of this product are listed as follows:

DACARBAZINE: NTP 7th Annual Report On Carcinogens; IARC Cancer Review: Group 2B (Possibly Carcinogenic to Humans, based on animal evidence. The carcinogenicity of Dacarbazine was studied in rats and mice. Cancers of the endocardium (the lining of the heart) and bladder were observed.

This product's other ingredients are not found on the following lists: FEDERAL OSHA Z LIST, NTP, IARC, CAL/OSHA, and therefore the ingredients are not considered to be, nor suspected to be, cancer-causing agents by these agencies.

IRRITANCY OF PRODUCT: This product may be irritating to contaminated skin, eyes, and other tissue.

SENSITIZATION TO THE PRODUCT: Citric Acid may cause sensitization of the skin after prolonged or repeated over-exposure.

REPRODUCTIVE TOXICITY INFORMATION: Listed below is information concerning the effects of this product and its components on the human reproductive system.

Mutagenicity: Human mutation data are available for Mannitol (a component of this product); these data were obtained during studies on specific human cells exposed to relatively high doses of this substance. Mutation data are available for Dacarbazine (a component of this product), obtained during clinical studies on microorganisms and animal cells exposed to relatively high doses of this substance.

Embryotoxicity: Animal studies indicate that Dacarbazine (a component of this product) may produce embryotoxic effects. In rabbits, doses of Dacarbazine seven times the human daily dose resulted in fetal skeletal abnormalities.

Teratogenicity: Animal studies indicate Dacarbazine (a component of this product) is teratogenic, when given in doses 20 times the human daily dose on day 12 of gestation.

Reproductive Toxicity: Animal studies indicate Dacarbazine (a component of this product) has potential reproductive effects. Dacarbazine, when administered in 10 times the daily dose to male rats did not effect the male libido, although females mated to male rats had higher instances of resorptions than controls.

A mutagen is a chemical which causes permanent changes to genetic material (DNA) such that the changes will propagate through generational lines. An embryotoxin is a chemical which causes damage to a developing embryo (i.e. within the first eight weeks of pregnancy in humans), but the damage does not propagate across generational lines. A teratogen is a chemical which causes damage to a developing fetus, but the damage does not propagate across generational lines. A reproductive toxin is any substance which interferes in any way with the reproductive process.

BIOLOGICAL EXPOSURE INDICES (BEIs): Currently there are no Biological Exposure Indices (BEIs) associated with

the components of this product.

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: Blood conditions, liver and kidney disorders, and skin conditions may be aggravated by over-exposures to this product (especially in doses approaching therapeutic levels for this product).

RECOMMENDATIONS TO PHYSICIANS: Dacarbazine is a potent cytotoxic antineoplastic drug. It should only be used by persons experienced in management of patients receiving this type therapy. In the event of an occupational over-exposure, treat symptoms and eliminate over-exposure.

12. ECOLOGICAL INFORMATION

ENVIRONMENTAL STABILITY: This product will be relatively stable under ambient environmental conditions.

EFFECT OF MATERIAL ON PLANTS or ANIMALS: This product may be harmful to contaminated plant and animal life. Refer to Section 11 (Toxicological Information) for additional information on this product's components and their effects on test animals.

EFFECT OF CHEMICAL ON AQUATIC LIFE: This product may be harmful to aquatic plant and animal life in contaminated bodies of water.

13. DISPOSAL CONSIDERATIONS

PREPARING WASTES FOR DISPOSAL: Waste disposal must be in accordance with appropriate Federal, State, and local regulations. This product, if unaltered by handling, may be disposed of by treatment at a permitted facility or as advised by your local hazardous waste regulatory authority. All gowns, gloves, and disposable materials used in the preparation or handling of this drug should be disposed of in accordance with established hazardous waste disposal procedures. Reusable equipment should be cleaned with soap and water. Incineration is recommended.

EPA WASTE NUMBER: Not applicable to wastes consisting only of this product.

14. TRANSPORTATION INFORMATION

THIS MATERIAL IS NOT HAZARDOUS AS DEFINED BY 49 CFR 172.101 BY THE U.S. DEPARTMENT OF TRANSPORTATION

PROPER SHIPPING NAME: Not applicable.

HAZARD CLASS NUMBER and DESCRIPTION: Not applicable.

UN IDENTIFICATION NUMBER: Not applicable.

PACKING GROUP: Not applicable.

DOT LABEL(S) REQUIRED: Not applicable.

NORTH AMERICAN EMERGENCY RESPONSE GUIDEBOOK NUMBER (1996): Not applicable.

MARINE POLLUTANT: No component of this product is listed as a Marine Pollutant (49 CFR 172.101, Appendix B).

TRANSPORT CANADA TRANSPORTATION OF DANGEROUS GOODS REGULATIONS: THIS MATERIAL IS NOT CONSIDERED AS DANGEROUS GOODS. Refer to the above paragraph for additional information.

15. REGULATORY INFORMATION

SARA REPORTING REQUIREMENTS: The components of this product are not subject to the reporting requirements of Sections 302, 304, and 313 of Title III of the Superfund Amendments and Reauthorization Act.

SARA THRESHOLD PLANNING QUANTITY: Not applicable.

TSCA INVENTORY STATUS: The components of this product are listed on the TSCA Inventory.

CERCLA REPORTABLE QUANTITIES (RQ): Not applicable.

CALIFORNIA PROPOSITION 65: Dacarbazine is on the California Proposition 65 lists. **WARNING**: This product contains a chemical known to the State of California to cause cancer.

OTHER FEDERAL REGULATIONS: Based on this product's use, the requirements of the OSHA Bloodborne Pathogen Standard (29 CFR 1910.1030) are applicable.

15. REGULATORY INFORMATION (Continued)

STATE REGULATORY INFORMATION: The components of this product are covered under the following specific State regulations (NONE indicates no special regulations were noted).

Alaska - Designated Toxic and Hazardous Substances: None.

California - Permissible Exposure Limits for Chemical Contaminants: None.

Florida - Substance List: Dacarbazine.

Illinois - Toxic Substance List: Dacarbazine.

Kansas - Section 302/313 List: None.

Massachusetts - Substance List: Dacarbazine.:

Minnesota - List of Hazardous Substances: None.

Missouri - Employer Information/Toxic Substance List: None.

New Jersey - Right to Know Hazardous Substance List: Dacarbazine.

North Dakota - List of Hazardous Chemicals, Reportable Quantities: None.

Pennsylvania - Hazardous Substance List: Dacarbazine.

Rhode Island - Hazardous Substance List: Dacarbazine.

Texas - Hazardous Substance List: None.

West Virginia - Hazardous Substance List: None.

Wisconsin - Toxic and Hazardous Substances: None.

LABELING (Precautionary Statements): **WARNING!** CONTAINS A CARCINOGEN, BASED ON ANIMAL TESTS. CAUSES SKIN AND EYE IRRITATION. ACCIDENTAL INJECTION CAN CAUSE ADVERSE HEALTH EFFECTS. MAY CAUSE ALLERGIC SKIN REACTIONS. Avoid contact with skin, eyes, and clothing. Avoid accidental injection. Wash thoroughly after handling. Use in well-ventilated area. Use gloves, safety glasses, and appropriate respiratory and body protection. Keep away from heat, sparks, and other sources of ignition. **FIRST-AID:** In case of skin or eye contact, flush with water for 15 minutes. If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. If ingested, do not induce vomiting. Get medical attention. **IN CASE OF FIRE:** Use water fog, dry chemical, CO₂, or "alcohol" foam. **IN CASE OF SPILL:** Pick-up material with damp sponge, then place in a suitable container. Rinse area with water. Consult Material Safety Data Sheet before use.

CYTOTOXIC AGENT. DACARBAZINE should be administered under the supervision of a qualified physician experienced in the use of cancer chemotherapeutic agents. Appropriate management of therapy and complications is possible only when adequate diagnostic and treatment facilities are readily available. Avoid over-exposure. Wash hands and arms thoroughly after handling Dacarbazine. Do not eat, drink, or smoke when handling Dacarbazine. Clean-up spills promptly. Store vials in a cool location, tightly closed, away from direct light. Aluminum needles or intravenous sets should not be used for preparation or administration of Dacarbazine.

In addition to standard pharmacy labeling practices, all syringes and IV bags containing this product should be labeled as follows:

SPECIAL HANDLING AND DISPOSAL REQUIRED

TARGET ORGANS: Skin, eyes (anticipated occupational exposures). Blood system, kidneys, liver (therapeutic doses).

WHMIS SYMBOLS: **D2A** (Materials Causing Other Toxic Effects).



16. OTHER INFORMATION

PREPARED BY:

CHEMICAL SAFETY ASSOCIATES, Inc.
9163 Chesapeake Drive,
San Diego, CA 92123-1002
619/565-0302

DATE OF PRINTING:

November 30, 1999

DEFINITIONS OF TERMS

A large number of abbreviations and acronyms appear on a MSDS. Some of these which are commonly used include the following:

CAS #: This is the Chemical Abstract Service Number which uniquely identifies each constituent. It is used for computer-related searching.

EXPOSURE LIMITS IN AIR

ACGIH - American Conference of Governmental Industrial Hygienists, a professional association which establishes exposure limits.

TLV - Threshold Limit Value - an airborne concentration of a substance which represents conditions under which it is generally believed that nearly all workers may be repeatedly exposed without adverse effect. The duration must be considered, including the 8-hour **Time Weighted Average (TWA)**, the 15-minute **Short Term Exposure Limit**, and the instantaneous **Ceiling Level**. Skin absorption effects must also be considered.

OSHA - U.S. Occupational Safety and Health Administration.

PEL - Permissible Exposure Limit - this exposure value means exactly the same as a TLV, except that it is enforceable by OSHA. The OSHA Permissible Exposure Limits are based in the 1989 PELs and the June, 1993 Air Contaminants Rule (Federal Register: 58: 35338-35351 and 58: 40191). Both the current PELs and the vacated PELs are indicated. The phrase, A Vacated 1989 PEL, is placed next to the PEL which was vacated by Court Order.

IDLH - Immediately Dangerous to Life and Health - This level represents a concentration from which one can escape within 30-minutes without suffering escape-preventing or permanent injury. **The DFG - MAK** is the Republic of Germany's Maximum Exposure Level, similar to the U.S. PEL. **NIOSH** is the National Institute of Occupational Safety and Health, which is the research arm of the U.S. Occupational Safety and Health Administration (**OSHA**). NIOSH issues exposure guidelines called **Recommended Exposure Levels (RELs)**. When no exposure guidelines are established, an entry of **NE** is made for reference.

FLAMMABILITY LIMITS IN AIR

Much of the information related to fire and explosion is derived from the **National Fire Protection Association (NFPA)**. **LEL** - the lowest percent of vapor in air, by volume, that will explode or ignite in the presence of an ignition source. **UEL** - the highest percent of vapor in air, by volume, that will explode or ignite in the presence of an ignition source.

TOXICOLOGICAL INFORMATION

Possible health hazards as derived from human data, animal studies, or from the results of studies with similar compounds are presented. Definitions of some terms used in this section are: **LD₅₀** - Lethal Dose (solids & liquids) which kills 50% of the exposed animals; **LC₅₀** - Lethal Concentration (gases) which kills 50% of the exposed animals; **ppm** concentration expressed in parts of material per million parts of air or water; **mg/m³** concentration expressed in weight of substance per volume of air; **mg/kg** quantity of material, by weight, administered to a test subject, based on their body weight in kg. Data from several sources are used to evaluate the cancer-causing potential of the material. The sources are: **IARC** - the International Agency for Research on Cancer; **NTP** - the National Toxicology Program, **RTECS** - the Registry of Toxic Effects of Chemical Substances, **OSHA** and **CAL/OSHA**. IARC and NTP rate chemicals on a scale of decreasing potential to cause human cancer with rankings from 1 to 4. Subrankings (2A, 2B, etc.) are also used. Other measures of toxicity include **TDL_o**, the lowest dose to cause a symptom and **TCL_o** the lowest concentration to cause a symptom; **TDo**, **LDLo**, and **LDo**, or **TC**, **TCo**, **LCLo**, and **LCo**, the lowest dose (or concentration) to cause death. **BEI** - Biological Exposure Indices, represent the levels of determinants which are most likely to be observed in specimens collected from a healthy worker who has been exposed to chemicals to the same extent as a worker with inhalation exposure to the TLV.

REGULATORY INFORMATION

This section explains the impact of various laws and regulations on the material. **EPA** is the U.S. Environmental Protection Agency. **WHMIS** is the Canadian Workplace Hazardous Materials Information System. **DOT** and **TC** are the U.S. Department of Transportation and Transport Canada, respectively. The following laws are pertinent to the information presented in the MSDS: **Superfund Amendments and Reauthorization Act (SARA)**; the **Toxic Substance Control Act (TSCA)**; Marine Pollutant status according to the **DOT**; California's Safe Drinking Water Act (**Proposition 65**); the **Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA or Superfund)**. This section also includes information on the precautionary warnings which appear on the materials package label.