



A Pfizer Company

SAFETY DATA SHEET

Revision date: 30-Aug-2018

Version: 1.2

Page 1 of 7

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

Product Identifier

Material Name: Dacarbazine for Injection (Hospira, Inc.)

Trade Name: Dacarbazine for Injection, USP

Chemical Family: Not determined

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Pharmaceutical product used as Antineoplastic

Details of the Supplier of the Safety Data Sheet

Hospira, A Pfizer Company
275 North Field Drive
Lake Forest, Illinois 60045
1-800-879-3477

Emergency telephone number (North America):
CHEMTREC (24 hours): 1-800-424-9300

Contact E-Mail: pfizer-MSDS@pfizer.com

Hospira Australia Pty Ltd
11 Lexia Place
Mulgrave VIC 3170
Australia

Emergency telephone number (Australia):
International CHEMTREC (24 hours): +1-703-527-3887

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification

Germ Cell Mutagenicity: Category 2

Reproductive Toxicity: Category 1B

Carcinogenicity: Category 2

Label Elements

Signal Word: Danger

Hazard Statements:
H341 - Suspected of causing genetic defects
H351 - Suspected of causing cancer
H360D - May damage the unborn child

Precautionary Statements:
P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P308 + P313 - IF exposed or concerned: Get medical attention/advice
P405 - Store locked up
P501 - Dispose of contents/container in accordance with all local and national regulations



SAFETY DATA SHEET

Material Name: Dacarbazine for Injection (Hospira, Inc.)
Revision date: 30-Aug-2018

Page 2 of 7
Version: 1.2

Other Hazards No data available
Note: This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Dacarbazine	4342-03-4	224-396-1	Muta 2 (H341)2 (H351)1B (H360D)	40-44
Citric Acid Monohydrate	5949-29-1	Not Listed	Not Listed	42-44

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Mannitol	69-65-8	200-711-8	Not Listed	*

Additional Information: * Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

For the full text of the CLP/GHS abbreviations mentioned in this Section, see [Section 16](#)

4. FIRST AID MEASURES

Description of First Aid Measures

Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Most Important Symptoms and Effects, Both Acute and Delayed

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

5. FIRE FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO₂, extinguishing powder, foam, or water.

SAFETY DATA SHEET

Material Name: Dacarbazine for Injection (Hospira, Inc.)
Revision date: 30-Aug-2018

Page 3 of 7
Version: 1.2

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire. Emits toxic fumes of carbon monoxide and oxides of nitrogen .

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

Advice for Fire-Fighters

During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Cleanup operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Precautions for Safe Handling

Minimize dust generation and accumulation. Avoid breathing dust. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging.

Specific end use(s): Pharmaceutical drug product

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

Refer to available public information for specific member state Occupational Exposure Limits.

Dacarbazine

Netherlands OEL - TWA 0.0009 mg/m³

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

Dacarbazine

Pfizer Occupational Exposure Band (OEB): OEB 4 (control exposure to the range of 1ug/m³ to <10ug/m³)

Exposure Controls

SAFETY DATA SHEET

Material Name: Dacarbazine for Injection (Hospira, Inc.)
Revision date: 30-Aug-2018

Page 4 of 7
Version: 1.2

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Engineering Controls:	Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.
Personal Protective Equipment:	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
Hands:	Impervious disposable gloves (e.g. Nitrile, etc.) (double recommended) if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)
Eyes:	Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)
Skin:	Impervious disposable protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)
Respiratory protection:	Whenever excessive air contamination (dust, mist, vapor) is generated, respiratory protection, with appropriate protection factors, should be used to minimize exposure. Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a full mask, P3 filter). (Respirators must meet the standards in accordance with EN136, EN143, ASTM F2704-10 or international equivalent.)

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Solid in vial	Color:	Ivory
Odor:	Odorless	Odor Threshold:	No data available.
Molecular Formula:	Mixture	Molecular Weight:	Mixture
Solvent Solubility:	Slightly soluble: Alcohols		
Water Solubility:	Slightly Soluble:		
pH:	3-4		
Melting/Freezing Point (°C):	205		
Boiling Point (°C):	No data available.		
Partition Coefficient: (Method, pH, Endpoint, Value)			
Citric Acid Monohydrate			
No data available			
Mannitol			
No data available			
Dacarbazine			
No data available			
Decomposition Temperature (°C):	No data available.		
Evaporation Rate (Gram/s):	No data available		
Vapor Pressure (kPa):	No data available		
Vapor Density (g/ml):	No data available		
Relative Density:	No data available		
Viscosity:	No data available		
Flammability:			
Autoignition Temperature (Solid) (°C):	No data available		
Flammability (Solids):	No data available		
Flash Point (Liquid) (°C):	No data available		
Upper Explosive Limits (Liquid) (% by Vol.):	No data available		
Lower Explosive Limits (Liquid) (% by Vol.):	No data available		

SAFETY DATA SHEET

Material Name: Dacarbazine for Injection (Hospira, Inc.)
Revision date: 30-Aug-2018

Page 5 of 7
Version: 1.2

10. STABILITY AND REACTIVITY

Reactivity: No data available
Chemical Stability: Stable under normal conditions of use.
Possibility of Hazardous Reactions
Oxidizing Properties: None
Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.
Incompatible Materials: As a precautionary measure, keep away from strong oxidizers
Hazardous Decomposition Products: Thermal decomposition products may include carbon monoxide, carbon dioxide and oxides of nitrogen.

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

General Information: The information included in this section describes the potential hazards of the individual ingredients.
Short Term: May cause eye irritation (based on components) .
Long Term: Animal studies have shown a potential to cause adverse effects on the fetus.
Known Clinical Effects: Adverse effects associated with therapeutic use include decreased red blood cell count (anemia), decreased white blood cells (leukopenia), thrombocytopenia, loss of appetite (anorexia), nausea, vomiting. Rare cases of serious liver damage and allergic reactions have been reported.

Acute Toxicity: (Species, Route, End Point, Dose)

Mannitol

Rat Oral LD 50 13500 mg/kg
Mouse Oral LD 50 22 g/kg

Dacarbazine

Rat Oral LD50 2147 mg/kg
Mouse Oral LD50 2032mg/kg
Rat Intravenous LD50 411mg/kg

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Dacarbazine

Embryo / Fetal Development Rabbit Intraperitoneal 5 mg/kg/day NOAEL Teratogenic, Fetotoxicity
Embryo / Fetal Development Rat Intraperitoneal 30 mg/kg LOEL Teratogenic

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Dacarbazine

In Vivo Micronucleus Rodent Positive
Bacterial Mutagenicity (Ames) Positive

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Dacarbazine

18 Month(s) Rat Oral Intraperitoneal Malignant tumors, Spleen, Brain, Thymus, Mammary gland

Carcinogen Status: See below

SAFETY DATA SHEET

Material Name: Dacarbazine for Injection (Hospira, Inc.)
Revision date: 30-Aug-2018

Page 6 of 7
Version: 1.2

11. TOXICOLOGICAL INFORMATION

Dacarbazine

IARC: Group 2B (Possibly Carcinogenic to Humans)
NTP: Reasonably Anticipated To Be A Human Carcinogen

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been investigated. Releases to the environment should be avoided.

Toxicity: No data available

Persistence and Degradability: No data available

Bio-accumulative Potential: No data available

Mobility in Soil: No data available

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, ADG or IMDG regulations.

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Dacarbazine

SAFETY DATA SHEET

Material Name: Dacarbazine for Injection (Hospira, Inc.)
Revision date: 30-Aug-2018

Page 7 of 7
Version: 1.2

15. REGULATORY INFORMATION

CERCLA/SARA 313 Emission reporting California Proposition 65	Not Listed carcinogen 1/1/1988 developmental toxicity 1/29/1999
Australia (AICS): Standard for the Uniform Scheduling for Drugs and Poisons: EU EINECS/ELINCS List	Present Schedule 4 224-396-1
Citric Acid Monohydrate	
CERCLA/SARA 313 Emission reporting California Proposition 65	Not Listed Not Listed
Australia (AICS): EU EINECS/ELINCS List	Present Not Listed
Mannitol	
CERCLA/SARA 313 Emission reporting California Proposition 65	Not Listed Not Listed
Inventory - United States TSCA - Sect. 8(b) Australia (AICS): REACH - Annex IV - Exemptions from the obligations of Register: EU EINECS/ELINCS List	Present Present Present 200-711-8

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3

Germ cell mutagenicity-Cat.2; H341 - Suspected of causing genetic defects
Carcinogenicity-Cat.2; H351 - Suspected of causing cancer
Reproductive toxicity-Cat.1B; H360D - May damage the unborn child

Data Sources: Pfizer proprietary drug development information. Publicly available toxicity information.

Reasons for Revision: Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking.

Revision date: 30-Aug-2018
Product Stewardship Hazard Communications

Prepared by: Pfizer Global Environment, Health, and Safety Operations

Pfizer Inc believes that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet