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

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
Other Hazards
Note: No data available
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

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

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mannitol</td>
<td>69-65-8</td>
<td>200-711-8</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

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
5. FIRE FIGHTING MEASURES

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

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 fire fighting 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. Clean up 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
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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**

- **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
- **Odor:** Odorless
- **Color:** Ivory
- **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 |
SAFETY DATA SHEET

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

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 LD 50 2147 mg/kg
- Mouse Oral LD 50 2032 mg/kg
- Rat Intravenous LD 50 411 mg/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)
11. TOXICOLOGICAL INFORMATION

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

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, or IMDG regulations.
15. REGULATORY INFORMATION

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

Dacarbazine
- CERCLA/SARA 313 Emission reporting: Not Listed
- Australia (AICS): Present
- Standard for the Uniform Scheduling for Drugs and Poisons: Schedule 4
- EU EINECS/ELINCS List: 224-396-1

Mannitol
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- REACH - Annex IV - Exemptions from the obligations of Register: Present
- EU EINECS/ELINCS List: 200-711-8

Citric Acid Monohydrate
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Australia (AICS): Present
- EU EINECS/ELINCS List: Not Listed

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.

Revision date: 29-Jul-2016
Prepared by: Product Stewardship Hazard Communication

Pfizer Inc believes that the information contained in this Material 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