**MATERIAL SAFETY DATA SHEET**

1. **IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING**

<table>
<thead>
<tr>
<th>Pfizer Inc</th>
<th>Pfizer Ltd</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pfizer Pharmaceuticals Group</td>
<td>Ramsgate Road</td>
</tr>
<tr>
<td>235 East 42nd Street</td>
<td>Sandwich, Kent</td>
</tr>
<tr>
<td>New York, New York 10017</td>
<td>CT13 9NJ</td>
</tr>
<tr>
<td>1-212-573-2222</td>
<td>United Kingdom</td>
</tr>
<tr>
<td>Emergency telephone number:</td>
<td>Emergency telephone number:</td>
</tr>
<tr>
<td>CHEMTREC (24 hours): 1-800-424-9300</td>
<td>ChemSafe (24 hours): +44 (0)208 762 8322</td>
</tr>
</tbody>
</table>

**Material Name:** Daunorubicin hydrochloride for injection

**Trade Name:** Daunoblastin

**Chemical Family:** Mixture

**Intended Use:** Pharmaceutical product used as Antineoplastic, antibiotic agent

2. **COMPOSITION/INFORMATION ON INGREDIENTS**

<table>
<thead>
<tr>
<th>Hazardous</th>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS List</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Daunorubicin Hydrochloride</td>
<td>23541-50-6</td>
<td>245-723-4</td>
<td>&lt;0.5</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS List</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water for injection</td>
<td>7732-18-5</td>
<td>231-791-2</td>
<td>*</td>
</tr>
<tr>
<td>Sodium chloride</td>
<td>7647-14-5</td>
<td>231-598-3</td>
<td>*</td>
</tr>
</tbody>
</table>

**Additional Information:**

* Proprietary

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

3. **HAZARDS IDENTIFICATION**

**Appearance:** Liquid

**Signal Word:** WARNING

**Statement of Hazard:**

May cause adverse effects on blood forming organs.

Suspected of damaging the unborn child.

Suspected of causing genetic defects.

Suspected of causing cancer.

May cause cardiovascular system effects

**Additional Hazard Information:**

**Short Term:** Harmful if swallowed (based on animal data). Drugs of this class have been associated with rare, but potentially serious cardiac events. These events have not been observed from occupational exposures, however, those with preexisting cardiovascular illnesses may be at increased risk from exposure.

**Long Term:** Repeat-dose studies in animals have shown a potential to cause adverse effects on testes and the developing fetus.

**Known Clinical Effects:** Effects on blood and blood-forming organs have also occurred.

**EU Indication of danger:** Not classified
MATERIAL SAFETY DATA SHEET

Material Name: Daunorubicin hydrochloride for injection
Revision date: 04-Jan-2007
Version: 1.1

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

4. FIRST AID MEASURES

Eye Contact: Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.

Skin Contact: Remove clothing and wash affected skin with soap and water. If irritation occurs or persists, get medical attention.

Ingestion: Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person. Get medical attention.

Inhalation: Remove to fresh air. If not breathing, give artificial respiration. Get medical attention.

5. FIRE FIGHTING MEASURES

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

Fire Fighting Procedures: During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

Fire / Explosion Hazards: Not applicable

6. ACCIDENTAL RELEASE MEASURES

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

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

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

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
General Handling: Avoid contact with eyes, skin and clothing. Avoid breathing vapor or mist. Use appropriate ventilation. When handling, use proper personal protective equipment as specified in Section 8. Wash thoroughly after handling.

Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Daunorubicin Hydrochloride

Pfizer OEL TWA-8 Hr: 0.1 ug/m³
The exposure limit(s) listed for solid components are only relevant if dust or mist may be generated.


Engineering Controls: Engineering controls should be used as the primary means to control exposures. Local exhaust ventilation is required unless used in a closed system.

Personal Protective Equipment:

Hands: Chemical protective gloves
Eyes: Safety glasses or goggles
Skin: Wear protective clothing with long sleeves to avoid skin contact. Wash hands and arms thoroughly after handling this product.
Respiratory protection: 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.

9. PHYSICAL AND CHEMICAL PROPERTIES:

Physical State: Liquid
Molecular Formula: Mixture

Color: Colorless
Molecular Weight: Mixture

10. STABILITY AND REACTIVITY

Stability: Stable under normal conditions of use.
Conditions to Avoid: None known
Incompatible Materials: As a precautionary measure, keep away from strong oxidizers.

11. TOXICOLOGICAL INFORMATION

General Information: The information included in this section describes the potential hazards of the individual ingredients.

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

Daunorubicin Hydrochloride
Rat Oral LD 50 336 mg/kg
Rat Intravenous LD50 13 mg/kg
Rat Intraperitoneal LD50 20 mg/kg
Mouse Oral LD50 205 mg/kg
Mouse Intravenous LD50 8.6 mg/kg

Sodium chloride
Irritation / Sensitization: (Study Type, Species, Severity)

Sodium chloride
Eye Irritation  Rabbit  Moderate
Skin Irritation  Rabbit  Mild

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Sodium chloride
10 Day(s)  Rat  Oral  12500 mg/kg  LOAEL  Kidney, Ureter, Bladder

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

Daunorubicin Hydrochloride
Embryo / Fetal Development  Rabbit  Oral  0.05 mg/kg/day  LOAEL  Teratogenic, Fetotoxicity
Embryo / Fetal Development  Rat  Oral  4 mg/kg/day  LOAEL  Teratogenic
Embryo / Fetal Development  Rabbit  Intravenous  1.5 mg/kg  LOAEL  Fetotoxicity, Fertility

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

Daunorubicin Hydrochloride
Bacterial Mutagenicity (Ames)  Salmonella  Positive
In Vitro Cytogenetics  Human Lymphocytes  Positive
In Vivo Micronucleus  Not applicable  Positive

Carcinogen Status:  See below

Daunorubicin Hydrochloride
IARC:  2B - Possibly Carcinogenic to Humans

12. ECOLOGICAL INFORMATION

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

13. DISPOSAL CONSIDERATIONS

Disposal Procedures:  Dispose of waste in accordance with all applicable laws and regulations.

14. TRANSPORT INFORMATION

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.
15. REGULATORY INFORMATION

EU Indication of danger: Not classified

OSHA Label:
WARNING
May cause adverse effects on blood forming organs.
Suspected of damaging the unborn child.
Suspected of causing genetic defects.
Suspected of causing cancer.
May cause cardiovascular system effects

Canada - WHMIS: Classifications

WHMIS hazard class:
Class D, Division 2, Subdivision A

Daunorubicin Hydrochloride
California Proposition 65 Listed: Developmental toxicity
Australia (AICS): Present
EU EINECS List 245-723-4

Water for injection
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS List 231-791-2

Sodium chloride
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS List 231-598-3

16. OTHER INFORMATION

Reasons for Revision:
Updated Section 3 - Hazard Identification. Updated Section 6 - Accidental Release Measures.
Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 10 - Stability
and Reactivity. Updated Section 13 - Disposal Considerations.

Prepared by:
Corporate Occupational Toxicology & Hazard Assessment

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.

End of Safety Data Sheet