# SAFETY DATA SHEET

**Revision date:** 03-Mar-2015  
**Version:** 2.0  
**Page 1 of 9**

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

**Product Identifier**

<table>
<thead>
<tr>
<th>Material Name: Idarubicin Hydrochloride Capsules (5 mg)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Trade Name:</strong> ZAVEDOS; IDAMYCIN</td>
</tr>
<tr>
<td><strong>Chemical Family:</strong> Mixture</td>
</tr>
</tbody>
</table>

**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**

- **Pfizer Inc**
  - Pfizer Pharmaceuticals Group
  - 235 East 42nd Street
  - New York, New York 10017
  - 1-800-879-3477

- **Pfizer Ltd**
  - Ramsgate Road
  - Sandwich, Kent
  - CT13 9NJ
  - United Kingdom
  - +00 44 (0)1304 616161

**Emergency telephone number:**

- CHEMTREC (24 hours): 1-800-424-9300
- International CHEMTREC (24 hours): +1-703-527-3887

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

## 2. HAZARDS IDENTIFICATION

**Classification of the Substance or Mixture**

**GHS - Classification**

- Acute Oral Toxicity: Category 3
- Germ Cell Mutagenicity: Category 2
- Reproductive Toxicity: Category 1B
- Carcinogenicity: Category 2

**EU Classification:**

- EU Indication of danger: Toxic
  - Toxic to Reproduction: Category 2
  - Mutagenic: Category 3
  - Carcinogenic: Category 3

**EU Risk Phrases:**

- R25 - Toxic if swallowed.
- R40 - Limited evidence of a carcinogenic effect.
- R60 - May impair fertility.
- R61 - May cause harm to the unborn child.
- R68 - Possible risk of irreversible effects.

**Label Elements**

<table>
<thead>
<tr>
<th>Signal Word:</th>
<th>Danger</th>
</tr>
</thead>
</table>

PZ00030
2. HAZARDS IDENTIFICATION

Hazard Statements:
- H301 - Toxic if swallowed
- H341 - Suspected of causing genetic defects
- H351 - Suspected of causing cancer
- H360FD - May damage fertility. May damage the unborn child.

Precautionary Statements:
- P202 - Do not handle until all safety precautions have been read and understood
- P264 - Wash hands thoroughly after handling
- P270 - Do not eat, drink or smoke when using this product
- P281 - Use personal protective equipment as required
- P301+P310 - IF SWALLOWED: Immediately call a POISON CENTRE or doctor/physician
- P321 - Specific treatment (see supplemental first aid instructions on this label)
- P330 - Rinse mouth
- P405 - Store locked up
- P501 - Dispose of contents/container in accordance with all local and national regulations

Other Hazards
Australian Hazard Classification (NOHSC):

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

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Idarubicin Hydrochloride</td>
<td>57852-57-0</td>
<td>260-990-7</td>
<td>T+;R28</td>
<td>Acute Tox.2 (H300) Carc.2 (H351) Muta.2 (H341) Rep. 1B (H360FD)</td>
<td>5%</td>
</tr>
<tr>
<td>Microcrystalline cellulose</td>
<td>9004-34-6</td>
<td>232-674-9</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glycerl Palmito-Stearate</td>
<td>None Assigned</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Hard gelatin capsules</td>
<td>MIXTURE</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>
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.

Special Hazards Arising from the Substance or Mixture

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

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

Prevent exposure by any route. Personnel must wear appropriate protective equipment (see Section 8).

Environmental Precautions

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

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
Restrict access to work area. Minimize dust generation and accumulation. If tablets or capsules are crushed and/or broken, avoid breathing dust and 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.

Idarubicin Hydrochloride
Pfizer OEL TWA-8 Hr: 0.1µg/m³

Microcrystalline cellulose
ACGIH Threshold Limit Value (TWA) 10 mg/m³
Australia TWA 10 mg/m³
Belgium OEL - TWA 10 mg/m³
Estonia OEL - TWA 10 mg/m³
France OEL - TWA 10 mg/m³
Ireland OEL - TWA 10 mg/m³
4 mg/m³
Latvia OEL - TWA 2 mg/m³
OSHA - Final PELS - TWAs: 15 mg/m³
Portugal OEL - TWA 10 mg/m³
Romania OEL - TWA 10 mg/m³
Russia OEL - TWA 6 mg/m³
Spain OEL - TWA 10 mg/m³
Switzerland OEL -TWAs 3 mg/m³
Vietnam OEL - TWAs 10 mg/m³
5 mg/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).
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

   Hands:
   Impervious, disposable gloves (double suggested) are recommended if skin contact with drug product is possible and for bulk processing operations.

   Eyes:
   Wear safety glasses or goggles if eye contact is possible.

   Skin:
   Impervious disposable protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

   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

   Solvent Solubility: No data available
   Water Solubility: No data available
   pH: No data available
   Melting/Freezing Point (°C): No data available
   Boiling Point (°C): No data available
   Partition Coefficient: (Method, pH, Endpoint, Value)
   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

10. STABILITY AND REACTIVITY

   Reactivity: No data available
   Chemical Stability: Stable under normal conditions of use.
   Possibility of Hazardous Reactions
      Oxidizing Properties: No data available
      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: No data available
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 skin irritation. (based on animal data).

Long Term:  Repeat-dose studies in animals have shown a potential to cause adverse effects on blood and blood forming organs, gastrointestinal system, lymphatic system, male reproductive system liver, kidneys, heart, and developing fetus.

Known Clinical Effects:  Bone marrow suppression is the most serious adverse effect seen during clinical use. Adverse effects associated with therapeutic use include effects on cardiovascular system, gastrointestinal system, liver, kidney, and skin rash. 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.

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

Idarubicin Hydrochloride

<table>
<thead>
<tr>
<th>Species</th>
<th>Route</th>
<th>End Point</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>Oral</td>
<td>LD50</td>
<td>5.43 mg/kg</td>
</tr>
<tr>
<td>Mouse</td>
<td>Oral</td>
<td>LD50</td>
<td>13.98 mg/kg</td>
</tr>
<tr>
<td>Rat</td>
<td>Intravenous</td>
<td>LD50</td>
<td>3.08 mg/kg</td>
</tr>
<tr>
<td>Mouse</td>
<td>Intravenous</td>
<td>LD50</td>
<td>4.10 mg/kg</td>
</tr>
<tr>
<td>Rabbit</td>
<td>Dermal</td>
<td>LD50</td>
<td>&gt; 40 mg/kg</td>
</tr>
</tbody>
</table>

Microcrystalline cellulose

<table>
<thead>
<tr>
<th>Species</th>
<th>Route</th>
<th>End Point</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>Oral</td>
<td>LD50</td>
<td>&gt; 5000 mg/kg</td>
</tr>
<tr>
<td>Rabbit</td>
<td>Dermal</td>
<td>LD50</td>
<td>&gt; 2000 mg/kg</td>
</tr>
</tbody>
</table>

Acute Toxicity Comments:   A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

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

Microcrystalline cellulose

<table>
<thead>
<tr>
<th>Type</th>
<th>Species</th>
<th>Severity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin Irritation</td>
<td>Rabbit</td>
<td>Non-irritating</td>
</tr>
<tr>
<td>Eye Irritation</td>
<td>Rabbit</td>
<td>Non-irritating</td>
</tr>
</tbody>
</table>

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

Idarubicin Hydrochloride

<table>
<thead>
<tr>
<th>Duration</th>
<th>Species</th>
<th>Route</th>
<th>Dose</th>
<th>NOAEL</th>
<th>Effected Systems</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 Month(s)</td>
<td>Dog</td>
<td>Oral</td>
<td>0.08 mg/kg/day</td>
<td>NOAEL</td>
<td>Blood forming organs, Immune system, Lymphatic system, Gastrointestinal system, Liver, Male reproductive system</td>
</tr>
<tr>
<td>13 Week(s)</td>
<td>Rat</td>
<td>Oral</td>
<td>0.192 mg/kg/day</td>
<td>NOAEL</td>
<td>Blood forming organs, Immune system, Lymphatic system, Kidney, Heart, Gastrointestinal system</td>
</tr>
<tr>
<td>13 Week(s)</td>
<td>Dog</td>
<td>Oral</td>
<td>0.15 mg/kg/day</td>
<td>NOAEL</td>
<td>Blood forming organs, Immune system, Lymphatic system, Gastrointestinal system, Liver</td>
</tr>
<tr>
<td>13 Week(s)</td>
<td>Rat</td>
<td>Intravenous</td>
<td>0.064 mg/kg/day</td>
<td>NOAEL</td>
<td>Blood forming organs, Immune system, Lymphatic system, Gastrointestinal system, Kidney, Heart</td>
</tr>
<tr>
<td>13 Week(s)</td>
<td>Dog</td>
<td>Intravenous</td>
<td>0.045 mg/kg/day</td>
<td>NOAEL</td>
<td>Blood forming organs, Immune system, Lymphatic system, Gastrointestinal system</td>
</tr>
</tbody>
</table>

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

Idarubicin Hydrochloride
Embryo / Fetal Development  Rat  Intravenous  0.195 mg/kg/day  LOAEL  Embryotoxicity, Teratogenic, Fetotoxicity
Embryo / Fetal Development  Rabbit  Intravenous  0.203 mg/kg/day  LOAEL  Not Teratogenic, Embryotoxicity, Maternal Toxicity
Fertility and Embryonic Development  Rat  Intravenous  0.01 mg/kg/day  LOAEL  Maternal Toxicity, Paternal toxicity, Fetotoxicity

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

Idarubicin Hydrochloride
Bacterial Mutagenicity (Ames)  Salmonella  Positive
Mitotic Gene Conversion  Not specified  Positive
In Vitro Mammalian Cell Mutagenicity  Hamster  Positive
In Vitro Chromosome Aberration  Human Lymphocytes  Positive

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

Idarubicin Hydrochloride
30 Week(s)  Rat  Intravenous  0.06 mg/kg/month  LOAEL  Benign tumors, Malignant tumors

Carcinogen Status:  None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

12. ECOLOGICAL INFORMATION

Environmental Overview:  The environmental characteristics of this material have not been fully evaluated. 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.
This material is regulated for transportation as a hazardous material/dangerous good.

**UN number:** UN 2811
**UN proper shipping name:** Toxic solid, organic, n.o.s. (Idarubicin hydrochloride)
**Transport hazard class(es):** 6.1
**Packing group:** III

Limited Quantity Exceptions apply to small quantities packed in combination packaging. See applicable modal regulations for specific limitations.

## 15. REGULATORY INFORMATION

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

**Canada - WHMIS: Classifications**
- **WHMIS hazard class:** Class D, Division 1, Subdivision B

**Idarubicin Hydrochloride**
- CERCLA/SARA 313 Emission reporting: Not Listed
  - California Proposition 65: developmental toxicity initial date 8/20/99
  - Male reproductive toxicity initial date 8/20/99
  - EU EINECS/ELINCS List: 260-990-7

**Glyceryl Palmito-Stearate**
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- EU EINECS/ELINCS List: Not Listed

**Hard gelatin capsules**
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- EU EINECS/ELINCS List: Not Listed

**Microcrystalline cellulose**
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>REACH - Annex XVII - Restrictions on Certain Dangerous Substances:</th>
<th>Use restricted. See item 9[f]. powder</th>
</tr>
</thead>
<tbody>
<tr>
<td>EU EINECS/ELINCS List</td>
<td>232-674-9</td>
</tr>
</tbody>
</table>

16. OTHER INFORMATION

Text of R phrases and GHS Classification abbreviations mentioned in Section 3

Acute toxicity, oral-Cat.2: H300 - Fatal if swallowed
Germ cell mutagenicity-Cat.2: H341 - Suspected of causing genetic defects
Carcinogenicity-Cat.2: H351 - Suspected of causing cancer
Reproductive toxicity-Cat.1B; H360FD - May damage fertility. May damage the unborn child.

Carcinogenic: Category 3
Mutagenic: Category 3
Toxic to Reproduction: Category 2
T+ - Very toxic

R28 - Very toxic if swallowed.
R40 - Limited evidence of a carcinogenic effect
R60 - May impair fertility.
R61 - May cause harm to the unborn child.
R68 - Possible risks of irreversible effects.

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

Reasons for Revision: Updated Section 7 - Handling and Storage. Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 11 - Toxicology Information. Updated Section 14 - Transport Information. Updated Section 16 - Other Information. Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 4 - First Aid Measures.

Revision date: 03-Mar-2015

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