# SAFETY DATA SHEET

**Revision date:** 02-Mar-2015  
**Version:** 3.0  
**Page:** 1 of 10

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

### Product Identifier

<table>
<thead>
<tr>
<th>Material Name: Idarubicin Hydrochloride Injection 1 mg/ml</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trade Name: Zavedos; Idamycin</td>
</tr>
<tr>
<td>Chemical Family: 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

<table>
<thead>
<tr>
<th>Supplier</th>
<th>Address</th>
<th>Contact Information</th>
</tr>
</thead>
</table>
| 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

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

## 2. HAZARDS IDENTIFICATION

### Classification of the Substance or Mixture

#### GHS - Classification

- Reproductive Toxicity: Category 1B

#### EU Classification:

- EU Indication of danger: Harmful
- EU Risk Phrases:
  - R22 - Harmful if swallowed.

### Label Elements

#### Signal Word: Danger

#### Hazard Statements:

- H360FD - May damage fertility. 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
- P281 - Use personal protective equipment as required
- 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
Australian Hazard Classification (NOHSC):

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

<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)</td>
<td>0.1</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Repr.Cat.2;R60</td>
<td>Carc.2 (H351)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Repr.Cat.2;R61</td>
<td>Muta.2 (H341)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Carc.Cat.3;R40</td>
<td>Repr. 1B (H360FD)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Mut.Cat.3;R68</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Glycero, USP</td>
<td>56-81-5</td>
<td>200-289-5</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Hydrochloric Acid</td>
<td>7647-01-0</td>
<td>231-595-7</td>
<td>T; R23</td>
<td>Press. Gas</td>
<td>**</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>C; R35</td>
<td>Skin Corr. 1A; H314</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Acute Tox. 3; H331</td>
<td></td>
</tr>
</tbody>
</table>

Additional Information:

* Proprietary
** to adjust pH
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 R phrases and 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.

Special Hazards Arising from the Substance or Mixture
Hazardous Combustion: Formation of toxic gases is possible during heating or fire.
Products:

Fire / Explosion Hazards: Not applicable

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 spill with absorbent material. 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
Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. Use with adequate ventilation. 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:

\[ 0.1 \mu g/m^3 \]

**Glycerin, USP**

<table>
<thead>
<tr>
<th>Location</th>
<th>OEL/TWA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Belgium</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Czech Republic</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Estonia</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Finland</td>
<td>20 mg/m³</td>
</tr>
<tr>
<td>France</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Germany (DFG) - MAK</td>
<td>50 mg/m³</td>
</tr>
<tr>
<td>Greece</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Ireland</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>OSHA - Final PELS - TWAs</td>
<td>15 mg/m³</td>
</tr>
<tr>
<td>Poland</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Portugal</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Spain</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Switzerland</td>
<td>50 mg/m³</td>
</tr>
</tbody>
</table>

**Hydrochloric Acid**

ACGIH Ceiling Threshold Limit:

- 2 ppm
- 7.5 mg/m³

<table>
<thead>
<tr>
<th>Location</th>
<th>OEL/TWA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia PEAK</td>
<td>5 ppm</td>
</tr>
<tr>
<td>Austria</td>
<td>5 ppm</td>
</tr>
<tr>
<td>Belgium</td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Bulgaria</td>
<td>5 ppm</td>
</tr>
<tr>
<td>Cyprus</td>
<td>5 ppm</td>
</tr>
<tr>
<td>Czech Republic</td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Estonia</td>
<td>5 ppm</td>
</tr>
<tr>
<td>Germany - TRGS 900 - TWAs</td>
<td>2 ppm</td>
</tr>
<tr>
<td>Germany (DFG) - MAK</td>
<td>2 ppm</td>
</tr>
<tr>
<td>Greece</td>
<td>5 ppm</td>
</tr>
<tr>
<td>Hungary</td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Ireland</td>
<td>5 ppm</td>
</tr>
<tr>
<td>Italy</td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Japan</td>
<td>5 ppm</td>
</tr>
<tr>
<td>Latvia</td>
<td>5 ppm</td>
</tr>
</tbody>
</table>

**OSHA - Final PELS - TWAs:**

- 15 mg/m³
- 3 mg/m³
- 3.0 mg/m³
- 7 mg/m³
- 8 mg/m³
- 7.5 mg/m³
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Analytical Method:
Analytical method available for Idarubicin. Contact Pfizer Inc for further information.

Exposure Controls:
Engineering controls should be used as the primary means to control exposures.

Personal Protective Equipment:
Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Hands:
Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

Eyes:
Wear safety glasses as minimum protection.

Skin:
Wear impervious protective clothing when handling this compound.

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:
Solution

Odor:
No data available.

Molecular Formula:
Mixture

Color:
Red-orange

Odor Threshold:
No data available.

Molecular Weight:
Mixture

Solvent Solubility:
No data available

Water Solubility:
No data available

pH:
3.5

Melting/Freezing Point (°C):
No data available

Boiling Point (°C):
No data available.

Partition Coefficient: (Method, pH, Endpoint, Value)

Idarubicin Hydrochloride
No data available

Water for Injection
No data available

Hydrochloric Acid
No data available
9. PHYSICAL AND CHEMICAL PROPERTIES

Glycerin, USP

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

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 eye and skin irritation (based on components)
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, 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, kidney, liver, 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
- Rat Oral LD50 5.43 mg/kg
- Mouse Oral LD50 13.98 mg/kg
- Rat Intravenous LD50 3.08 mg/kg
- Mouse Intravenous LD50 4.10 mg/kg
- Rabbit Dermal LD50 > 40 mg/kg

Glycerin, USP

PZ01148
11. TOXICOLOGICAL INFORMATION

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)

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

Idarubicin Hydrochloride

3 Month(s) Dog Oral 0.08 mg/kg/day NOAEL Blood forming organs, Immune system, Lymphatic system, Gastrointestinal System, Liver, Male reproductive system
13 Week(s) Rat Oral 0.192 mg/kg/day NOAEL Blood forming organs, Immune system, Lymphatic system, Kidney, Heart, Liver, Gastrointestinal system
13 Week(s) Dog Oral 0.15 mg/kg/day NOAEL Blood forming organs, Immune system, Lymphatic system, Gastrointestinal system, Liver
13 Week(s) Rat Intravenous 0.064 mg/kg/day NOAEL Blood forming organs, Immune system, Lymphatic system, Gastrointestinal system, Kidney, Heart
13 Week(s) Dog Intravenous 0.045 mg/kg/day NOAEL Blood forming organs, Immune system, Lymphatic system, Gastrointestinal system

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

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
11. TOXICOLOGICAL INFORMATION

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

Hydrochloric Acid IARC: Group 3 (Not Classifiable)

12. ECOLOGICAL INFORMATION

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

Toxicity:

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

Glycerin, USP  
*Oncorhynchus mykiss* (Rainbow Trout)  
**LD50** 96 Hours 50 mg/L

*Daphnia magna* (Water Flea)  
**EC50** 24 Hours >500 mg/L

Aquatic Toxicity Comments: A greater than symbol (>) indicates that aquatic toxicity was not observed at the maximum dose tested.

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

Canada - WHMIS: Classifications
WHMIS hazard class:
Class D, Division 2, Subdivision A

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

Glycerin, USP
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 V - Exemptions from the obligations of Register:
Present if not chemically modified, except they meet the criteria for classification as dangerous according to Directive 67/548/EEC, except those only classified as flammable [R10], as a skin irritant [R38] or as an eye irritant [R36], except they are persistent, bioaccumulative, and toxic or very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII, except they were identified in accordance with Article 59[1] at least two years previously as substances giving rise to an equivalent level of concern
200-289-5

Hydrochloric Acid
CERCLA/SARA 313 Emission reporting 1.0 %
CERCLA/SARA Hazardous Substances 5000 lb
and their Reportable Quantities:
2270 kg
CERCLA/SARA - Section 302 Extremely Hazardous
TPQs 500 lb
CERCLA/SARA - Section 302 Extremely Hazardous
Substances EPCRA RQs Not Listed
California Proposition 65
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
Standard for the Uniform Scheduling for Drugs and Poisons:
Schedule 5
EU EINECS/ELINCS List Schedule 6
231-595-7
15. REGULATORY INFORMATION

Water for Injection

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: 231-791-2

16. OTHER INFORMATION

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

Acute toxicity, oral-Cat.2; H302 - Harmful if swallowed
Acute toxicity, inhalation-Cat.3; H331 - Toxic if inhaled
Carcinogenicity-Cat.2; H351 - Suspected of causing cancer
Germ cell mutagenicity-Cat.2; H341 - Suspected of causing genetic defects
Reproductive toxicity-Cat.1B; H360FD - May damage fertility. May damage the unborn child.
Skin corrosion/irritation-Cat.1A; H314 - Causes severe skin burns and eye damage

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

R23 - Toxic by inhalation.
R28 - Very toxic if swallowed.
R35 - Causes severe burns.
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 1 - Identification of the Substance/Preparation and the Company/Undertaking.
- Updated Section 3 - Composition / Information on Ingredients.
- Updated Section 15 - Regulatory Information.
- Updated Section 2 - Hazard Identification.
- Updated Section 7 - Handling and Storage.
- Updated Section 4 - First Aid Measures.
- Updated Section 11 - Toxicology Information.
- Updated Section 16 - Other Information.

Revision date: 02-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