



# SAFETY DATA SHEET

Revision date: 15-Mar-2018

Version: 4.1

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

### Product Identifier

**Material Name:** Idarubicin Hydrochloride Powder for Injection

**Trade Name:** IDAMYCIN; ZAVEDOS

**Chemical Family:** Anthracycline

### 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

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

### Emergency telephone number:

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

## 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

#### US OSHA Specific - Classification

**Physical Hazard:** Combustible Dust

### Label Elements

**Signal Word:** Danger

**Hazard Statements:**  
H301 - Toxic if swallowed  
H360FD - May damage fertility. May damage the unborn child.  
H351 - Suspected of causing cancer  
H341 - Suspected of causing genetic defects  
May form combustible dust concentrations in air

**Precautionary Statements:**  
P201 - Obtain special instructions before use  
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  
P308 + P313 - IF exposed or concerned: Get medical attention/advice  
P405 - Store locked up

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### Other Hazards

An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

### 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	%
Idarubicin Hydrochloride	57852-57-0	260-990-7	Acute Tox.2 (H300) Carc.2 (H351) Muta.2 (H341) Repr. 1B (H360FD)	10

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Lactose NF, anhydrous	63-42-3	200-559-2	Not Listed	*

### Additional Information:

\* Proprietary

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

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

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**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 CO<sub>2</sub>, extinguishing powder, foam, or water.

#### Special Hazards Arising from the Substance or Mixture

**Hazardous Combustion Products:** Toxic gases including carbon monoxide and oxides of nitrogen can be expected in fires of this material.

**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

Restrict access to work area. 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 hands and any exposed skin after removal of PPE. It is recommended that all operations be fully enclosed and no air recirculated. 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 Antineoplastic

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Control Parameters

Idarubicin Hydrochloride  
Pfizer OEL TWA-8 Hr:

0.1µg/m<sup>3</sup>

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### 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. It is recommended that all operations be fully enclosed and no air recirculated.

##### Personal Protective Equipment:

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

##### 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:

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:** Freeze-dried preparation  
**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  
**Solubility:** Soluble: Water  
**pH:** No data available.  
**Melting/Freezing Point (°C):** No data available  
**Boiling Point (°C):** No data available.

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

#### Idarubicin Hydrochloride

No data available

#### Lactose NF, anhydrous

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

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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:** Nitrogen oxides (nox) carbon monoxide and carbon dioxide

### 11. TOXICOLOGICAL INFORMATION

#### Information on Toxicological Effects

**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 the developing fetus. Individuals sensitive to this chemical or other materials in its chemical class may develop allergic reactions.

**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

Rat Oral LD50 5.43 mg/kg  
Mouse Oral LD50 13.98 mg/kg  
Rat Intravenous LD50 3.08mg/kg  
Mouse Intravenous LD50 4.10mg/kg  
Rabbit Dermal LD50 > 40mg/kg

**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.

#### 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

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### 11. TOXICOLOGICAL INFORMATION

#### 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 Toxicity	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)	<i>Salmonella</i>	Positive
Mitotic Gene Conversion	Not specified	Positive
<i>In Vitro</i> Mammalian Cell Mutagenicity	Hamster	Positive
<i>In Vitro</i> 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
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**Carcinogen Status:** Not listed as a carcinogen by IARC, NTP or US OSHA.

### 12. ECOLOGICAL INFORMATION

<b>Environmental Overview:</b>	Environmental properties have not been investigated. Releases to the environment should be avoided.
<b>Toxicity:</b>	No data available
<b>Persistence and Degradability:</b>	No data available
<b>Bio-accumulative Potential:</b>	No data available
<b>Mobility in Soil:</b>	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.

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### 14. TRANSPORT INFORMATION

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

This material is regulated for transport under DOT, ADR, IMDG, and IATA regulations.

UN number: UN 3249  
UN proper shipping name: Medicine, solid, toxic, n.o.s  
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

#### Lactose NF, anhydrous

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	200-559-2

#### Idarubicin Hydrochloride

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	developmental toxicity 8/20/1999 male reproductive toxicity 8/20/99
EU EINECS/ELINCS List	260-990-7

### 16. OTHER INFORMATION

#### Text of CLP/GHS Classification abbreviations mentioned in Section 3

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

Data Sources: Publicly available toxicity information. Pfizer proprietary drug development information.  
Reasons for Revision: Updated Section 8 - Exposure Controls / Personal Protection.  
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**Prepared by:** Product Stewardship Hazard Communication  
Pfizer Global Environment, Health, and Safety Operations

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**End of Safety Data Sheet**