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
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

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
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

<table>
<thead>
<tr>
<th>Hazardous Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</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>Acute Tox.2 (H300) Carc.2 (H351) Muta.2 (H341) Repr. 1B (H360FD)</td>
<td>10</td>
</tr>
</tbody>
</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>Lactose NF, anhydrous</td>
<td>63-42-3</td>
<td>200-559-2</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

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
SAFETY DATA SHEET

Material Name: Idarubicin Hydrochloride Powder for Injection
Revision date: 15-Mar-2018

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: 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/m³
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
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)

<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>Rat</td>
<td>Oral</td>
<td>NOAEL</td>
<td>Blood forming organs, Immune system, Lymphatic system, Gastrointestinal system, Liver, Male reproductive system</td>
</tr>
<tr>
<td>Dog</td>
<td>Oral</td>
<td>NOAEL</td>
<td>Blood forming organs, Immune system, Lymphatic system, Gastrointestinal system, Kidney, Heart, Liver, Male reproductive system</td>
</tr>
<tr>
<td>Dog</td>
<td>Oral</td>
<td>NOAEL</td>
<td>Blood forming organs, Immune system, Lymphatic system, Gastrointestinal system, Kidney, Heart</td>
</tr>
<tr>
<td>Dog</td>
<td>Intravenous</td>
<td>NOAEL</td>
<td>Blood forming organs, Immune system, Lymphatic system, Gastrointestinal system, Kidney, Heart</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.

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

<table>
<thead>
<tr>
<th>Duration</th>
<th>Species</th>
<th>Route</th>
<th>End Point</th>
<th>Dose</th>
<th>NOAEL</th>
<th>Target Organ</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 Month(s)</td>
<td>Dog</td>
<td>Oral</td>
<td>NOAEL</td>
<td>Blood forming organs, Immune system, Lymphatic system, Gastrointestinal system, Liver, Male reproductive system</td>
<td></td>
<td></td>
</tr>
<tr>
<td>13 Week(s)</td>
<td>Rat</td>
<td>Oral</td>
<td>NOAEL</td>
<td>Blood forming organs, Immune system, Lymphatic system, Kidney, Heart, Liver, Gastrointestinal system</td>
<td></td>
<td></td>
</tr>
<tr>
<td>13 Week(s)</td>
<td>Dog</td>
<td>Oral</td>
<td>NOAEL</td>
<td>Blood forming organs, Immune system, Lymphatic system, Gastrointestinal system, Kidney, Heart</td>
<td></td>
<td></td>
</tr>
<tr>
<td>13 Week(s)</td>
<td>Rat</td>
<td>Intravenous</td>
<td>NOAEL</td>
<td>Blood forming organs, Immune system, Lymphatic system, Gastrointestinal system, Kidney, Heart</td>
<td></td>
<td></td>
</tr>
<tr>
<td>13 Week(s)</td>
<td>Dog</td>
<td>Intravenous</td>
<td>NOAEL</td>
<td>Blood forming organs, Immune system, Lymphatic system, Gastrointestinal system</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

PZ00025
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  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:  Not listed as a carcinogen by IARC, NTP or US OSHA.

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.

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

<table>
<thead>
<tr>
<th>UN number</th>
<th>UN 3249</th>
</tr>
</thead>
<tbody>
<tr>
<td>UN proper shipping name</td>
<td>Medicine, solid, toxic, n.o.s</td>
</tr>
<tr>
<td>Transport hazard class(es)</td>
<td>6.1</td>
</tr>
<tr>
<td>Packing group</td>
<td>III</td>
</tr>
</tbody>
</table>

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.

Revision date: 15-Mar-2018
SAFETY DATA SHEET

Material Name: Idarubicin Hydrochloride Powder for Injection
Revision date: 15-Mar-2018

Prepared by:
Product Stewardship Hazard Communication
Pfizer Global Environment, Health, and Safety Operations

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