# SAFETY DATA SHEET

**Product Identifier**

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

**Trade Name:** Adriamycin, Adriblastina; Adriblastin; Adriblastina; Farmiblastina; Adriblastin; Adriacin; Pfizer Doxorubicin

**Synonyms:** Doxorubicin RDF Injection

**Chemical Family:** Mixture

## Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

**Intended Use:** Pharmaceutical product used as Antineoplastic

## Classification of the Substance or Mixture

**GHS - Classification**

- Germ Cell Mutagenicity: Category 1B
- Reproductive Toxicity: Category 1B
- Carcinogenicity: Category 1B

**US OSHA Specific - Classification**

- **Physical Hazard:** Combustible Dust

**Signal Word:** Danger

**Hazard Statements:**

- H340 - May cause genetic defects
- H350 - May cause cancer
- H360FD - May damage fertility. May damage the unborn child. May form combustible dust concentrations in air

**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

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**Revision date:** 21-Jun-2017

**Version:** 4.1

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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

<table>
<thead>
<tr>
<th>Hazardous</th>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Doxorubicin Hydrochloride</td>
<td>25316-40-9</td>
<td>246-818-3</td>
<td>Muta.1B (H340) Carc.1B (H350) Repr.1B (H360FD)</td>
<td>16.4</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>Methylparaben</td>
<td>99-76-3</td>
<td>202-785-7</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Lactose</td>
<td>63-42-3</td>
<td>200-559-2</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

Additional Information:

* Proprietary

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 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.
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.

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
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. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Precautions for Safe Handling
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. 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
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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Doxorubicin Hydrochloride
Pfizer OEL TWA-8 Hr: 0.5 µg/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). 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: Lyophilized powder
Odor: No data available.
Molecular Formula: Mixture

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)

Doxorubicin Hydrochloride
No data available
Lactose
No data available
Methylparaben
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:

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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.
Long Term: Repeat-dose studies in animals have shown a potential to cause adverse effects on testes, the developing fetus.
Known Clinical Effects: Bone marrow suppression is the most serious adverse effect seen during clinical use. 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)

Doxorubicin Hydrochloride
- Mouse Oral LD 50 698 mg/kg
- Mouse Para-periosteal LD 50 1.2 mg/kg
- Rat Intravenous LD 50 12.5 mg/kg
- Rat Intraperitoneal LD 50 16 mg/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.

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

Doxorubicin Hydrochloride
- Reproductive & Fertility-Females Rat Intraperitoneal 0.05 mg/kg/day LOAEL Fertility
- Reproductive & Fertility-Males Rat Intraperitoneal 0.1 mg/kg/day LOAEL Fertility
- Embryo / Fetal Development Rat Intraperitoneal 0.8 mg/kg/day LOAEL Teratogenic, Embryotoxicity
- Embryo / Fetal Development Rabbit Intraperitoneal 0.4 mg/kg/day LOAEL Embryotoxicity

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

Doxorubicin Hydrochloride
- Bacterial Mutagenicity (Ames) Salmonella, E. coli Positive
## 11. TOXICOLOGICAL INFORMATION

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Species/Cell Line</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>In Vivo Micronucleus</td>
<td>Mouse</td>
<td>Positive</td>
</tr>
<tr>
<td>In Vitro Chromosome Aberration</td>
<td>Chinese Hamster Ovary (CHO) cells</td>
<td>Positive</td>
</tr>
<tr>
<td>In Vitro Sister Chromatid Exchange</td>
<td>Human Lymphocytes</td>
<td>Positive</td>
</tr>
<tr>
<td>Dominant Lethal Assay</td>
<td>Mouse</td>
<td>Positive</td>
</tr>
</tbody>
</table>

**Carcinogen Status:** See below

**Doxorubicin Hydrochloride**
- **IARC:** 2A
- **NTP:** Reasonably Anticipated To Be A Human Carcinogen

## 12. ECOLOGICAL INFORMATION

**Environmental Overview:** Environmental properties have not been thoroughly 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.

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**

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15. REGULATORY INFORMATION

Methylparaben

- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- EU EINECS/ELINCS List: 202-785-7

Lactose

- 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

Doxorubicin Hydrochloride

- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: carcinogen 7/1/1987
carcinogen 1/29/1999
developmental toxicity 1/29/1999
male reproductive toxicity 1/29/1999
- EU EINECS/ELINCS List: 246-818-3

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3

- Reproductive toxicity-Cat.1B; H360FD - May damage fertility. May damage the unborn child.
- Germ cell mutagenicity-Cat.1B; H340 - May cause genetic defects
- Carcinogenicity-Cat.1B; H350 - May cause cancer

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

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection.

Revision date: 21-Jun-2017

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