



# SAFETY DATA SHEET

Revision date: 25-Jan-2018

Version: 4.1

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

### Product Identifier

**Material Name:** Doxorubicin Hydrochloride Solution for Injection - 2 mg/ml

**Trade Name:** Adriamycin, ADRIABLASTINA; ADRIBLASTIN; ADRIABLASTINA; ADIBLASTINE

**Chemical Family:** Mixture

### 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  
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**CHEMTREC (24 hours): 1-800-424-9300**  
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**Emergency telephone number:**  
**International CHEMTREC (24 hours): +1-703-527-3887**

## 2. HAZARDS IDENTIFICATION

### Classification of the Substance or Mixture

#### GHS - Classification

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

### Label Elements

**Signal Word:** Danger  
**Hazard Statements:** H340 - May cause genetic defects  
H350 - May cause cancer  
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

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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	%
Doxorubicin Hydrochloride	25316-40-9	246-818-3	Muta.1B (H340) Carc.1B (H350) Repr.1B (H360FD)	0.2
Hydrochloric Acid	7647-01-0	231-595-7	Press. Gas Skin Corr.1A (H314) Acute Tox.3 (H331)	**

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Water for injection	7732-18-5	231-791-2	Not Listed	*
Sodium chloride	7647-14-5	231-598-3	Not Listed	*

### 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 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.

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**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 CO<sub>2</sub>, 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 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 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. Cleanup operations should only be undertaken by trained personnel.

## 7. HANDLING AND STORAGE

### Precautions for Safe Handling

Restrict access to work area. Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). 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.

**Storage Temperature:** 2-8°C (36-46°F)

**Specific end use(s):** Pharmaceutical drug product

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Control Parameters

Refer to available public information for specific member state Occupational Exposure Limits.

#### Doxorubicin Hydrochloride

Pfizer OEL TWA-8 Hr: 0.5 µg/m<sup>3</sup>

#### Sodium chloride

Latvia OEL - TWA 5 mg/m<sup>3</sup>

Lithuania OEL - TWA 5 mg/m<sup>3</sup>

#### Hydrochloric Acid

ACGIH Ceiling Threshold Limit: 2 ppm

Australia PEAK 5 ppm

7.5 mg/m<sup>3</sup>

Austria OEL - MAKs 5 ppm

8 mg/m<sup>3</sup>

Belgium OEL - TWA 5 ppm

8 mg/m<sup>3</sup>

Bulgaria OEL - TWA 5 ppm

8.0 mg/m<sup>3</sup>

Cyprus OEL - TWA 5 ppm

8 mg/m<sup>3</sup>

Czech Republic OEL - TWA 8 mg/m<sup>3</sup>

Estonia OEL - TWA 5 ppm

8 mg/m<sup>3</sup>

Germany - TRGS 900 - TWAs 2 ppm

3 mg/m<sup>3</sup>

Germany (DFG) - MAK 2 ppm

3.0 mg/m<sup>3</sup>

Greece OEL - TWA 5 ppm

7 mg/m<sup>3</sup>

Hungary OEL - TWA 8 mg/m<sup>3</sup>

Ireland OEL - TWAs 5 ppm

8 mg/m<sup>3</sup>

Italy OEL - TWA 5 ppm

8 mg/m<sup>3</sup>

Japan - OELs - Ceilings 2 ppm

3.0 mg/m<sup>3</sup>

Latvia OEL - TWA 5 ppm

8 mg/m<sup>3</sup>

Lithuania OEL - TWA 5 ppm

8 mg/m<sup>3</sup>

Luxembourg OEL - TWA 5 ppm

8 mg/m<sup>3</sup>

Malta OEL - TWA 5 ppm

8 mg/m<sup>3</sup>

Netherlands OEL - TWA 8 mg/m<sup>3</sup>

Poland OEL - TWA 5 mg/m<sup>3</sup>

Portugal OEL - TWA 5 ppm

8 mg/m<sup>3</sup>

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Romania OEL - TWA	5 ppm 8 mg/m <sup>3</sup>
Slovakia OEL - TWA	5 ppm 8.0 mg/m <sup>3</sup>
Slovenia OEL - TWA	5 ppm 8 mg/m <sup>3</sup>
Spain OEL - TWA	5 ppm 7.6 mg/m <sup>3</sup>
Switzerland OEL -TWAs	2 ppm 3.0 mg/m <sup>3</sup>
Vietnam OEL - TWAs	5 mg/m <sup>3</sup>

#### Sodium chloride

**Pfizer Occupational Exposure Band (OEB):** OEB 1 (control exposure to the range of 1000ug/m<sup>3</sup> to 3000ug/m<sup>3</sup>)

#### 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:

Solution

#### Color:

Red

#### Odor:

No data available.

#### Odor Threshold:

No data available.

#### Molecular Formula:

Mixture

#### Molecular Weight:

Mixture

#### Solvent Solubility:

No data available

#### Water Solubility:

No data available

#### pH:

3.0

#### Melting/Freezing Point (°C):

No data available

#### Boiling Point (°C):

No data available.

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

Doxorubicin Hydrochloride

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### 9. PHYSICAL AND CHEMICAL PROPERTIES

No data available

**Water for injection**

No data available

**Sodium chloride**

No data available

**Hydrochloric Acid**

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 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

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### 11. TOXICOLOGICAL INFORMATION

Rat Intraperitoneal LD 50 16 mg/kg

#### Sodium chloride

Rat Oral LD50 3000 mg/kg  
Mouse Oral LD50 4000 mg/kg

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

##### Sodium chloride

Eye Irritation Rabbit Moderate  
Skin Irritation Rabbit Mild

##### Hydrochloric Acid

Skin Irritation Severe  
Eye Irritation Severe

#### Reproduction & 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  
*In Vivo* Micronucleus Mouse Positive  
*In Vitro* Chromosome Aberration Chinese Hamster Ovary (CHO) cells Positive  
*In Vitro* Sister Chromatid Exchange Human Lymphocytes Positive  
Dominant Lethal Assay Mouse Positive

**Carcinogen Status:** See below

##### Doxorubicin Hydrochloride

IARC: 2A  
NTP: Reasonably Anticipated To Be A Human Carcinogen

##### Hydrochloric Acid

IARC: Group 3 (Not Classifiable)

### 12. ECOLOGICAL INFORMATION

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

**Toxicity:** No data available

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**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

**Doxorubicin Hydrochloride**

CERCLA/SARA 313 Emission reporting  
California Proposition 65

Not Listed  
carcinogen 7/1/1987  
developmental toxicity 1/29/1999  
male reproductive toxicity 1/29/99  
246-818-3

EU EINECS/ELINCS List

**Water for injection**

CERCLA/SARA 313 Emission reporting  
California Proposition 65  
Inventory - United States TSCA - Sect. 8(b)  
Australia (AICS):  
REACH - Annex IV - Exemptions from the obligations of Register:

Not Listed  
Not Listed  
Present  
Present  
Present



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### 15. REGULATORY INFORMATION

EU EINECS/ELINCS List 231-791-2

#### Sodium chloride

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	231-598-3

#### Hydrochloric Acid

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

### 16. OTHER INFORMATION

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

Germ cell mutagenicity-Cat.1B; H340 - May cause genetic defects  
Carcinogenicity-Cat.1B; H350 - May cause cancer  
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  
Acute toxicity, inhalation-Cat.3; H331 - Toxic if inhaled

<b>Data Sources:</b>	Pfizer proprietary drug development information. Publicly available toxicity information.
<b>Reasons for Revision:</b>	Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information.
<b>Revision date:</b>	25-Jan-2018 Product Stewardship Hazard Communication
<b>Prepared by:</b>	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**