



# SAFETY DATA SHEET

Revision date 16-Jun-2025

Version 6

Page 1 / 14

## Section 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

### 1.1. Product identifier

**Product Name** Doxorubicin Hydrochloride Solution for Injection - 2 mg/ml  
**Product Code(s)** PZ00059  
**Trade Name:** Adriamycin; ADRIABLASTINA; ADRIBLASTIN; ADRIBLASTINA; ADIBLASTINE  
**Chemical Family:** Mixture

### 1.2. Relevant identified uses of the substance or mixture and uses advised against

**Recommended Use** Pharmaceutical product used as Antineoplastic

### 1.3. Details of the supplier of the safety data sheet

Pfizer Inc  
66 Hudson Boulevard East  
New York, New York 10001  
1-800-879-3477

Pfizer Ireland Pharmaceuticals  
OSG Building  
Ringaskiddy, Co. Cork.  
Ireland  
+353 21 4378701

**E-mail address** pfizer-MSDS@pfizer.com

### 1.4. Emergency telephone number

**Emergency Telephone** Chemtrec 1-800-424-9300 International Chemtrec (24 hours):+1-703-527-3887

## Section 2: HAZARDS IDENTIFICATION

### 2.1. Classification of the substance or mixture

GHS - Classification: Regulated according to Regulation (EC) 1272/2008 and/or other applicable regulations.

**Germ cell mutagenicity**

Category 1B - (H340)

**Carcinogenicity**

Category 1B - (H350)

**Reproductive toxicity**

Category 1B - (H360FD)

### OSHA Classification

**Hazards not otherwise classified (HNOC)**

Not applicable

**Hazards classified under paragraph (d)(1)(ii) of 1910.1200**

Not applicable

### 2.2. Label elements



# SAFETY DATA SHEET

Product Name Doxorubicin Hydrochloride Solution for Injection - 2 mg/ml  
Revision date 16-Jun-2025

Page 2 / 14  
Version 6

**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 - EU (§28, 1272/2008)** 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 advice/attention  
P405 - Store locked up  
P501 - Dispose of contents/container in accordance with local, regional, national, and international regulations as applicable

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

**PBT & vPvB** The product does not contain any substance(s) classified as PBT or vPvB.

**Endocrine Disruptor Information** This product does not contain any known or suspected endocrine disruptors.

**Note:** This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

## Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

**3.1 Substances**  
**Substances** Not applicable

### 3.2 Mixtures

Hazardous

Chemical name	Weight-%	REACH registration number	EC No (EU Index No)	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Doxorubicin Hydrochloride (CAS #: 25316-40-9)	0.2		246-818-3	Muta.1B (H340) Carc.1B (H350) Repr.1B (H360FD) Aquatic Acute 2 (H401) Aquatic Chronic 2 (H411)	Not classified	No data available	No data available
+ Hydrochloric Acid (CAS #: 7647-01-0)	**	-	231-595-7 (017-002-00-2) (017-002-01-X)	Press. Gas Skin Corr. 1A (H314)	Eye Irrit. 2 :: 10%<=C<25% Skin Corr. 1B ::	No data available	No data available

# SAFETY DATA SHEET

Product Name Doxorubicin Hydrochloride Solution for Injection - 2 mg/ml  
Revision date 16-Jun-2025

Page 3 / 14  
Version 6

				Acute Tox. 3 (H331)	C>=25% Skin Irrit. 2 :: 10%<=C<25% STOT SE 3 :: C>=10%		
NonHazardous							
Chemical name	Weight-%	REACH registration number	EC No (EU Index No)	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Water (CAS #: 7732-18-5)	*	-	231-791-2	Not classified	Not classified	No data available	No data available
SODIUM CHLORIDE (CAS #: 7647-14-5)	*	-	231-598-3	Not classified	Not classified	No data available	No data available

**Full text of H- and EUH-phrases: see section 16**

Acute Toxicity Estimate

Chemical name	Oral LD50 mg/kg	Dermal LD50 mg/kg	Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapor - mg/L	Inhalation LC50 - 4 hour - gas - ppm
Water 7732-18-5	89838.9	No data available	No data available	No data available	No data available
SODIUM CHLORIDE 7647-14-5	3550	10000	No data available	No data available	No data available
+ Hydrochloric Acid 7647-01-0	238	5010	No data available	No data available	563.3022

This product does not contain candidate substances of very high concern at a concentration  $\geq 0.1\%$  (Regulation (EC) No. 1907/2006 (REACH), Article 59).

## Additional information

+ Substance with a Union workplace exposure limit

\* Proprietary

\*\* to adjust pH

Non-hazardous ingredients provided for completeness. 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.

## Section 4: FIRST AID MEASURES

### 4.1. Description of first aid measures

<b>Inhalation</b>	Remove to fresh air. Seek immediate medical attention/advice.
<b>Eye contact</b>	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
<b>Skin contact</b>	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
<b>Ingestion</b>	Never give anything by mouth to an unconscious person. Wash out mouth with water. Do

# SAFETY DATA SHEET

Product Name Doxorubicin Hydrochloride Solution for Injection - 2 mg/ml  
Revision date 16-Jun-2025

Page 4 / 14  
Version 6

not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

## **4.2. Most important symptoms and effects, both acute and delayed**

**Most important symptoms and effects** For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

## **4.3. Indication of any immediate medical attention and special treatment needed**

**Note to physicians** None.

## **Section 5: FIRE-FIGHTING MEASURES**

### **5.1. Extinguishing media**

**Suitable Extinguishing Media** Dry chemical, CO<sub>2</sub>, alcohol-resistant foam or water spray.

### **5.2. Special hazards arising from the substance or mixture**

**Specific hazards arising from the chemical** Fine particles (such as dust and mists) may fuel fires/explosions.

**Hazardous combustion products** Formation of toxic gases is possible during heating or fire.

#### **Explosion data**

**Sensitivity to mechanical impact** No information available.

**Sensitivity to static discharge** No information available.

### **5.3. Advice for firefighters**

**Special protective equipment and precautions for fire-fighters** Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

## **Section 6: ACCIDENTAL RELEASE MEASURES**

### **6.1. Personal precautions, protective equipment and emergency procedures**

**Personal precautions** Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

**For emergency responders** Use personal protection recommended in Section 8.

### **6.2. Environmental precautions**

**Environmental precautions** Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

### **6.3. Methods and material for containment and cleaning up**

**Methods for containment** Prevent further leakage or spillage if safe to do so.

**Methods for cleaning up** Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

**Prevention of secondary hazards** Clean contaminated objects and areas thoroughly observing environmental regulations.

### **6.4. Reference to other sections**

**Reference to other sections** See section 8 for more information. See section 13 for more information.

# SAFETY DATA SHEET

Product Name Doxorubicin Hydrochloride Solution for Injection - 2 mg/ml  
Revision date 16-Jun-2025

Page 5 / 14  
Version 6

## Section 7: HANDLING AND STORAGE

### 7.1. Precautions for safe handling

#### Advice on safe handling

Restrict access to work area. Avoid breathing dust/fume/gas/mist/vapors/spray. Avoid contact with skin, eyes or 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.

#### General hygiene considerations

Handle in accordance with good industrial hygiene and safety practice.

### 7.2. Conditions for safe storage, including any incompatibilities

#### Storage Conditions

Store as directed by product packaging.

### 7.3. Specific end use(s)

#### Specific use(s)

Pharmaceutical drug product.

## Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1. Control parameters

#### Exposure Limits

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

TWA: 5 mg/m<sup>3</sup>;

Russia

MAC: 5 mg/m<sup>3</sup>

#### Doxorubicin Hydrochloride

Poland

TWA-NDS: 0.0003 mg/m<sup>3</sup>; inhalable fraction  
Sk

#### + Hydrochloric Acid

ACGIH OEL (Ceiling)

2 ppm

ACGIH TLV

Ceiling: 2 ppm

Austria

TWA-TMW: 5 ppm;

TWA-TMW: 8 mg/m<sup>3</sup>;

STEL-KZGW: 10 ppm (8 X 5 min);

STEL-KZGW: 15 mg/m<sup>3</sup> (8 X 5 min);

Bulgaria

TWA: 5 ppm;

TWA: 8.0 mg/m<sup>3</sup>;

STEL: 10 ppm;

STEL: 15.0 mg/m<sup>3</sup>;

Czech Republic

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

Ceiling: 15 mg/m<sup>3</sup>

Denmark

STEL: 5 ppm;

STEL: 8 mg/m<sup>3</sup>;

Estonia

TWA: 5 ppm;

TWA: 8 mg/m<sup>3</sup>;

STEL: 10 ppm;

STEL: 15 mg/m<sup>3</sup>;

European Union

TWA: 5 ppm;

TWA: 8 mg/m<sup>3</sup>;

# SAFETY DATA SHEET

Product Name Doxorubicin Hydrochloride Solution for Injection - 2 mg/ml  
Revision date 16-Jun-2025

Page 6 / 14  
Version 6

	STEL: 10 ppm; STEL: 15 mg/m <sup>3</sup> ;
Finland	STEL: 5 ppm; STEL: 7.6 mg/m <sup>3</sup> ;
Germany DFG	TWA-MAK: 2 ppm; I(2); TWA-MAK: 3.0 mg/m <sup>3</sup> ; I(2); Peak: 4 ppm; Peak: 6 mg/m <sup>3</sup> ;
Germany TRGS	TWA-AGW; 2 ppm (exposure factor 2); TWA-AGW; 3 mg/m <sup>3</sup> (exposure factor 2);
Hungary	TWA-AK: 8 mg/m <sup>3</sup> ; TWA-AK: 5 ppm; STEL-CK: 165 mg/m <sup>3</sup> ;
Ireland	STEL-CK: 10 ppm; TWA: 8 mg/m <sup>3</sup> ; TWA: 5 ppm;
Italy MDLPS	STEL: 10 ppm; STEL: 15 mg/m <sup>3</sup> ; TWA: 5 ppm; TWA: 8 mg/m <sup>3</sup> ;
Ceiling Limit Value	STEL: 10 ppm; STEL: 15 mg/m <sup>3</sup> ; 2 ppm 3.0 mg/m <sup>3</sup>
Latvia	TWA: 5 ppm; TWA: 8 mg/m <sup>3</sup> ;
Netherlands	STEL: 10 ppm; STEL: 15 mg/m <sup>3</sup> ; TWA: 5 ppm; TWA: 8 mg/m <sup>3</sup> ;
Poland	STEL: 10 ppm; STEL: 15 mg/m <sup>3</sup> ;
Romania	TWA-NDS: 5 mg/m <sup>3</sup> ; STEL-NDSch: 10 mg/m <sup>3</sup> ;
Russia	TWA: 5 ppm; TWA: 8 mg/m <sup>3</sup> ;
Slovakia	STEL: 10 ppm; STEL: 15 mg/m <sup>3</sup> ; MAC: 5 mg/m <sup>3</sup>
Spain	TWA: 5 ppm; TWA: 8.0 mg/m <sup>3</sup> ; Ceiling: 15 mg/m <sup>3</sup> ;
Switzerland	TWA-(VLA-ED): 5 ppm; TWA-(VLA-ED): 7.6 mg/m <sup>3</sup> ; STEL (VLA-EC): 10 ppm; STEL (VLA-EC): 15 mg/m <sup>3</sup> ;
U.S. - OSHA - Final PELs - Ceiling Limits	TWA-MAK: 2 ppm; TWA-MAK: 3 mg/m <sup>3</sup> ;
OSHA PEL	STEL-KZGW: 4 ppm; STEL-KZGW: 6 mg/m <sup>3</sup> ;
United Kingdom	5 ppm 7 mg/m <sup>3</sup> Ceiling: 5 ppm Ceiling: 7 mg/m <sup>3</sup> (vacated) Ceiling: 5 ppm (vacated) Ceiling: 7 mg/m <sup>3</sup> TWA: 1 ppm; gas and aerosol mist TWA: 2 mg/m <sup>3</sup> ; gas and aerosol mist

# SAFETY DATA SHEET

Product Name Doxorubicin Hydrochloride Solution for Injection - 2 mg/ml  
Revision date 16-Jun-2025

Page 7 / 14  
Version 6

STEL: 5 ppm; gas and aerosol mist  
STEL: 8 mg/m<sup>3</sup>; gas and aerosol mist

## 8.2. 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.

### Eye/face protection

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.).

### Hand protection

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.).

### Skin and body protection

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.).

### Thermal hazards

No information available.

### Environmental exposure controls

No information available.

## Section 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1. Information on basic physical and chemical properties

#### Appearance

Solution

#### Physical state

Liquid

#### Color

Red

#### Odor

No information available.

#### Odor threshold

No information available

#### Property

#### Values

#### Melting point / freezing point

No data available

#### Boiling point or initial boiling point and boiling range

No data available

#### Flammability (solid, gas)

No data available

#### Lower and upper explosion limit/flammability limit

# SAFETY DATA SHEET

Product Name Doxorubicin Hydrochloride Solution for Injection - 2 mg/ml  
Revision date 16-Jun-2025

Page 8 / 14  
Version 6

Lower explosion limit	No data available
Upper explosion limit	No data available
Flash point	No data available
Autoignition temperature	No data available
Decomposition temperature	
SADT (°C)	No data available
pH	3.0
pH (as aqueous solution)	No data available
Kinematic viscosity	No data available
Dynamic viscosity	No data available
Solubility	No data available
Vapor pressure	No data available
Density and/or relative density	No data available
Bulk density	No data available
Liquid Density	No data available
Vapor density	No data available
Particle characteristics	
Particle Size	No information available
Particle Size Distribution	No information available

## 9.2. Other information

Molecular formula	Mixture
Molecular weight	Mixture

### 9.2.1. Information with regard to physical hazard classes

No information available

### 9.2.2. Other safety characteristics

No information available

## Section 10: STABILITY AND REACTIVITY

### 10.1. Reactivity

Reactivity No information available.

### 10.2. Chemical stability

Stability Stable under normal conditions.

### Explosion data

Sensitivity to mechanical impact No information available.

Sensitivity to static discharge No information available.

### 10.3. Possibility of hazardous reactions

Possibility of hazardous reactions No information available.

### 10.4. Conditions to avoid

Conditions to avoid Fine particles (such as dust and mists) may fuel fires/explosions.

### 10.5. Incompatible materials

Incompatible materials As a precautionary measure, keep away from strong oxidizers.

### 10.6. Hazardous decomposition products

Hazardous decomposition products No data available.

## Section 11: TOXICOLOGICAL INFORMATION

### 11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008



# SAFETY DATA SHEET

Product Name Doxorubicin Hydrochloride Solution for Injection - 2 mg/ml  
Revision date 16-Jun-2025

Page 9 / 14  
Version 6

<b>General Information:</b>	The information included in this section describes the potential hazards of the individual ingredients
<b>Short term</b>	May cause eye and skin irritation (based on components)
<b>Long Term:</b>	Repeat-dose studies in animals have shown a potential to cause adverse effects on testes the developing fetus.
<b>Known Clinical Effects:</b>	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.
<b>Acute toxicity</b>	Based on available data, the classification criteria are not met.
<b>Serious eye damage/eye irritation</b>	Based on available data, the classification criteria are not met.
<b>Skin corrosion/irritation</b>	Based on available data, the classification criteria are not met.
<b>Respiratory or skin sensitization</b>	Based on available data, the classification criteria are not met.
<b>STOT - single exposure</b>	Based on available data, the classification criteria are not met.
<b>STOT - repeated exposure</b>	Based on available data, the classification criteria are not met.
<b>Reproductive toxicity</b>	May damage fertility. May damage the unborn child.
<b>Germ cell mutagenicity</b>	May cause genetic defects.
<b>Carcinogenicity</b>	May cause cancer.
<b>Aspiration hazard</b>	Based on available data, the classification criteria are not met.

## **Acute Toxicity: (Species, Route, End Point, Dose)**

### **SODIUM CHLORIDE**

Rat Sub-tenon injection (eye) LC50/1hr > 42 g/m<sup>3</sup>

Rat Oral LD 50 3 g/kg

Mouse Oral LD 50 4 g/kg

Rabbit Dermal LD 50 > 10 g/kg

### **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

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Water	> 90 mL/kg ( Rat )	-	-
SODIUM CHLORIDE	= 3550 mg/kg ( Rat )	> 10000 mg/kg ( Rabbit )	> 42 mg/L ( Rat ) 1 h
+ Hydrochloric Acid	238 - 277 mg/kg ( Rat )	> 5010 mg/kg ( Rabbit )	= 1.68 mg/L ( Rat ) 1 h

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

### **SODIUM CHLORIDE**

Skin irritation Rabbit Mild

Eye irritation Rabbit Mild

### **+ Hydrochloric Acid**

Skin irritation Severe

Eye irritation Severe

## **Reproduction & Development Toxicity: (Duration, 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

# SAFETY DATA SHEET

Product Name Doxorubicin Hydrochloride Solution for Injection - 2 mg/ml  
Revision date 16-Jun-2025

Page 10 / 14  
Version 6

## 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

### + Hydrochloric Acid

Bacterial Mutagenicity (Ames) *Salmonella* Negative  
*In Vivo* Micronucleus Rat Negative

**Carcinogenicity** See below

### Doxorubicin Hydrochloride

IARC 2A  
NTP Reasonably Anticipated

### + Hydrochloric Acid

IARC Group 3

## 11.2. Information on other hazards

### 11.2.1. Endocrine disrupting properties

**Endocrine disrupting properties** Based on available data, the classification criteria are not met.

### 11.2.2. Other information

**Other adverse effects** No information available.

## Section 12: ECOLOGICAL INFORMATION

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

### 12.1. Toxicity

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

##### Doxorubicin

*Brachydanio rerio* (Zebra fish) OECD LC50 96 hours 68 mg/L  
*Brachydanio rerio* (Zebra fish) OECD NOEC 96 hours 46 mg/L  
*Daphnia Magna* (Water Flea) OECD EC50 48 hours 1.8 mg/L  
*Daphnia magna* (Water Flea) OECD NOEC 48 hours 0.07 mg/L

#### Bacterial Inhibition: (Inoculum, Method, End Point, Result)

##### Doxorubicin

Activated sludge OECD MIC - EC50 > 1000 mg/L

#### Chronic Aquatic Toxicity: (Species, Method, Duration, Endpoint, Result, Adverse Endpoint)

##### Doxorubicin

*Pseudokirchneriella subcapitata* (Green Alga) OECD 72 Hours EC50 4.1 mg/L Reproduction  
*Pseudokirchneriella subcapitata* (Green Alga) OECD 72 Hours NOEC 1.9 mg/L Reproduction

### 12.2. Persistence and degradability

**Persistence and degradability** No information available.

### 12.3. Bioaccumulative potential

**Bioaccumulation** No information available.

# SAFETY DATA SHEET

Product Name Doxorubicin Hydrochloride Solution for Injection - 2 mg/ml  
Revision date 16-Jun-2025

Page 11 / 14  
Version 6

## 12.4. Mobility in soil

**Mobility in soil** No information available.

## 12.5. Results of PBT and vPvB assessment

### PBT and vPvB assessment

Chemical name	PBT and vPvB assessment
SODIUM CHLORIDE	Not PBT/vPvB PBT assessment does not apply
+ Hydrochloric Acid	Not PBT/vPvB PBT assessment does not apply

## 12.6. Endocrine disrupting properties

**Endocrine disrupting properties** Based on available data, the classification criteria are not met.

## 12.7. Other adverse effects

**Other adverse effects** No information available.

**PMT or vPvM properties** Based on available data, the classification criteria are not met.

## Section 13: DISPOSAL CONSIDERATIONS

### 13.1. Waste treatment methods

#### Waste from residues/unused products

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 wastewater 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.

## Section 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.**

**UN number:** Not applicable  
**UN proper shipping name:** Not applicable  
**Transport hazard class(es):** Not applicable  
**Packing group:** Not applicable  
**Environmental Hazard(s):** Not applicable

## Section 15: REGULATORY INFORMATION

# SAFETY DATA SHEET

Product Name Doxorubicin Hydrochloride Solution for Injection - 2 mg/ml  
Revision date 16-Jun-2025

Page 12 / 14  
Version 6

## 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Water

<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>TSCA</b>	Present
<b>EINECS</b>	231-791-2
<b>AICS</b>	Present

SODIUM CHLORIDE

<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>TSCA</b>	Present
<b>EINECS</b>	231-598-3
<b>AICS</b>	Present

Doxorubicin Hydrochloride

<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Carcinogen
	Developmental
	Male Reproductive
<b>EINECS</b>	246-818-3

+ Hydrochloric Acid

<b>CERCLA/SARA Section 313 de minimus %</b>	1.0 %
<b>Hazardous Substances RQs</b>	5000 lb
<b>California Proposition 65</b>	Not Listed
<b>TSCA</b>	Present
<b>EINECS</b>	231-595-7
<b>AICS</b>	Present
<b>Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)</b>	Schedule 5
	Schedule 6

### National regulations

#### France

##### Occupational Illnesses (R-463-3, France)

Chemical name	French RG number
SODIUM CHLORIDE 7647-14-5	RG 78

#### Germany

##### Chemical Prohibition Ordinance (ChemVerbotsV)

Not applicable

#### TRGS 905

Not applicable

#### Switzerland

Ordinance on the Incentive Tax on Volatile Organic Compounds (OVOC) SR 814.018 Not applicable

Storage of Hazardous Material

Not applicable

WPO (GSchV) SR 814.201; WPA (GSchG) SR 814.20

Not applicable

Major Accidents Ordinance SR 814.012

Not applicable

#### European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.

#### **Authorizations and/or restrictions on use:**

This product contains one or more substance(s) subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

# SAFETY DATA SHEET

Product Name Doxorubicin Hydrochloride Solution for Injection - 2 mg/ml  
Revision date 16-Jun-2025

Page 13 / 14  
Version 6

Chemical name	Restricted substance per REACH Annex XVII	Substance subject to authorization per REACH Annex XIV
+ Hydrochloric Acid 7647-01-0	75	-

## Persistent Organic Pollutants

Not applicable

## Named dangerous substances per Seveso Directive (2012/18/EU)

Chemical name	Lower-tier requirements (tons)	Upper-tier requirements (tons)
+ Hydrochloric Acid 7647-01-0	25	250

## Ozone-depleting substances (ODS) Regulation (EU) 2024/590

Not applicable.

## EU - Plant Protection Products (1107/2009/EC)

Chemical name	EU - Plant Protection Products (1107/2009/EC)
SODIUM CHLORIDE 7647-14-5	Plant protection agent

## Biocidal Products Regulation (EU) No 528/2012 (BPR)

Chemical name	Biocidal Products Regulation (EU) No 528/2012 (BPR)
SODIUM CHLORIDE 7647-14-5	Product-type 1: Human hygiene
+ Hydrochloric Acid 7647-01-0	Product-type 2: Disinfectants and algaecides not intended for direct application to humans or animals

## Explosives Precursors Marketing and Use (2019/1148)

Not applicable

### Legend:

**TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory  
**DSL/NDL** - Canadian Domestic Substances List/Non-Domestic Substances List  
**EINECS/ELINCS** - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances  
**ENCS** - Japan Existing and New Chemical Substances  
**IECSC** - China Inventory of Existing Chemical Substances  
**KECL** - Korean Existing Chemicals Inventory  
**PICCS** - Philippines Inventory of Chemicals and Chemical Substances  
**AICS** - Australian Inventory of Chemical Substances  
**NZIoC** - New Zealand Inventory of Chemicals  
**TCSI** - Taiwan Chemical Substance Inventory

## 15.2. Chemical safety assessment

Chemical Safety Report No information available

## Section 16: OTHER INFORMATION

### Key or legend to abbreviations and acronyms used in the safety data sheet

### Full text of any hazard and/or precautionary statements referred to under Sections 2-15

H340 - May cause genetic defects. H350 - May cause cancer. H360FD - May damage fertility. May damage the unborn child. H314

# SAFETY DATA SHEET

Product Name Doxorubicin Hydrochloride Solution for Injection - 2 mg/ml  
Revision date 16-Jun-2025

Page 14 / 14  
Version 6

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- Causes severe skin burns and eye damage. H331 - Toxic if inhaled. H401 - Toxic to aquatic life. H411 - Toxic to aquatic life with long lasting effects.

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

**Reason for revision** Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information. Updated Section 15 - Regulatory Information. Updated Section 16 - Other Information.

**Revision date** 16-Jun-2025

**Prepared By** Pfizer Global Environment, Health, and Safety

**Pfizer Inc believes that the information contained in this 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.**