



MATERIAL SAFETY DATA SHEET

Revision date: 16-Mar-2011

Version: 3.0

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1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

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

Trade Name: Adriamycin, ADRIBLASTINA, FARMIBLASTINA
Chemical Family: Mixture
Intended Use: Pharmaceutical product used as Antineoplastic

2. HAZARDS IDENTIFICATION

Appearance: Red solution
Signal Word: DANGER

Statement of Hazard: May damage fertility or the unborn child.
May cause cancer.
May cause genetic defects.

Additional Hazard Information:

Short Term: May cause eye and skin irritation (based on components) . Effects of ingestion are not known. Avoid swallowing this material. 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.

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.

EU Indication of danger: Mutagenic: Category 2
Carcinogenic: Category 2
Toxic to Reproduction: Category 2

EU Hazard Symbols:



EU Risk Phrases:

R45 - May cause cancer.
R46 - May cause heritable genetic damage.
R60 - May impair fertility.
R61 - May cause harm to the unborn child.

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2. HAZARDS IDENTIFICATION

Australian Hazard Classification (NOHSC): Hazardous Substance. Non-Dangerous Goods.

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates 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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Doxorubicin Hydrochloride	25316-40-9	246-818-3	Repr.Cat.2;R60-61 Carc.Cat.2;R45 Mut.Cat.2;R46	0.2
Hydrochloric Acid	7647-01-0	231-595-7	C;R35 T;R23	**

Ingredient	CAS Number	EU EINECS/ELINCS List	EU 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.

For the full text of the R phrases mentioned in this Section, see Section 16

4. 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.

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.

5. FIRE FIGHTING MEASURES

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

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Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

Fire Fighting Procedures: During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

6. ACCIDENTAL RELEASE MEASURES

Health and Safety Precautions: Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

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.

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

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

General 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.

Storage Conditions: Store in a refrigerated area. Protect from light.

Storage Temperature: 2 - 8°C (36-45°F)

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Doxorubicin Hydrochloride	
Pfizer OEL TWA-8 Hr:	0.5 µg/m ³
Sodium chloride	
Latvia OEL - TWA	Listed
Lithuania OEL - TWA	Listed
Hydrochloric Acid	
ACGIH Ceiling Threshold Limit:	2 ppm
Australia PEAK	5 ppm
	7.5 mg/m ³
Austria OEL - MAKs	Listed
Belgium OEL - TWA	Listed
Bulgaria OEL - TWA	Listed
Cyprus OEL - TWA	Listed
Czech Republic OEL - TWA	Listed
Estonia OEL - TWA	Listed

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Germany - TRGS 900 - TWAs	2 ppm 3 mg/m ³
Germany (DFG) - MAK	2 ppm MAK 3.0 mg/m ³ MAK
Greece OEL - TWA	Listed
Hungary OEL - TWA	Listed
Ireland OEL - TWAs	Listed
Italy OEL - TWA	Listed
Japan - OELs - Ceilings	5 ppm 7.5 mg/m ³
Latvia OEL - TWA	Listed
Lithuania OEL - TWA	Listed
Luxembourg OEL - TWA	Listed
Malta OEL - TWA	Listed
Netherlands OEL - TWA	Listed
Poland OEL - TWA	Listed
Romania OEL - TWA	Listed
Slovenia OEL - TWA	Listed
Spain OEL - TWA	Listed

Analytical Method:	Analytical method available for Doxorubicin Hydrochloride. Contact Pfizer Inc for further information.
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.
Environmental Exposure Controls:	Refer to specific Member State legislation for requirements under Community environmental legislation.
Personal Protective Equipment:	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
Hands:	Impervious, disposable gloves (double suggested) are recommended if skin contact with drug product is possible and for bulk processing operations.
Eyes:	Wear safety glasses or goggles if eye contact is possible.
Skin:	Impervious disposable protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.
Respiratory protection:	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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Solution	Color:	Red
Molecular Formula:	Mixture	Molecular Weight:	Mixture
pH:	3.0		

10. STABILITY AND REACTIVITY

Chemical Stability:	Stable under normal conditions of use.
Conditions to Avoid:	None known
Incompatible Materials:	As a precautionary measure, keep away from strong oxidizers

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11. TOXICOLOGICAL INFORMATION

General Information: The information included in this section describes the potential hazards of the individual ingredients.

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

Sodium chloride

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

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

Hydrochloric Acid

Skin Irritation Severe
Eye Irritation Severe

Sodium chloride

Eye Irritation Rabbit Moderate
Skin Irritation Rabbit Mild

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

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: Listed
OSHA: Present

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11. TOXICOLOGICAL INFORMATION

Hydrochloric Acid

IARC: Group 3

12. ECOLOGICAL INFORMATION

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

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

EU Symbol: T
EU Indication of danger: Mutagenic: Category 2
Carcinogenic: Category 2
Toxic to Reproduction: Category 2

EU Risk Phrases:
R45 - May cause cancer.
R46 - May cause heritable genetic damage.
R60 - May impair fertility.
R61 - May cause harm to the unborn child.

EU Safety Phrases:
S23 - Do not breathe fumes/vapour/spray.
S36/37 - Wear suitable protective clothing and gloves.
S53 - Avoid exposure - obtain special instructions before use.

OSHA Label:
DANGER

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15. REGULATORY INFORMATION

May damage fertility or the unborn child.
May cause cancer.
May cause genetic defects.

Canada - WHMIS: Classifications

WHMIS hazard class:

D2a very toxic materials



Doxorubicin Hydrochloride

California Proposition 65

Listed: Developmental Toxicity, Cancer, and Male Reproductive
Toxicity

EU EINECS/ELINCS List

246-818-3

Water for injection

Inventory - United States TSCA - Sect. 8(b)

Listed

Australia (AICS):

Listed

REACH - Annex IV - Exemptions from the
obligations of Register:

Present

EU EINECS/ELINCS List

231-791-2

Sodium chloride

Inventory - United States TSCA - Sect. 8(b)

Listed

Australia (AICS):

Listed

EU EINECS/ELINCS List

231-598-3

Hydrochloric Acid

CERCLA/SARA 313 Emission reporting

1.0% de minimis concentration acid aerosols including mists,
vapors, gas, fog, and other airborne forms of any particle size

CERCLA/SARA Hazardous Substances
and their Reportable Quantities:

2270 kg final RQ

5000 lb final RQ

CERCLA/SARA - Section 302 Extremely Hazardous
TPQs

500 lb TPQ gas only

CERCLA/SARA - Section 302 Extremely Hazardous
Substances EPCRA RQs

5000 lb

Inventory - United States TSCA - Sect. 8(b)

Listed

Australia (AICS):

Listed

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 R phrases mentioned in Section 3

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R23 - Toxic by inhalation.

R35 - Causes severe burns.

R45 - May cause cancer.

R46 - May cause heritable genetic damage.

R60 - May impair fertility.

R61 - May cause harm to the unborn child.

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

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 10 - Stability and Reactivity.

Prepared by: Product Stewardship Hazard Communications
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