



MATERIAL SAFETY DATA SHEET

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

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Material Name: Epirubicin Hydrochloride Injection

Trade Name: Ellence, Farmorubicin; Pharmorubicin
Chemical Family: Anthracycline
Intended Use: Pharmaceutical product used as Antineoplastic

2. HAZARDS IDENTIFICATION

Appearance: Clear Red Solution
Signal Word: WARNING

Statement of Hazard: Suspected of causing cancer.
Suspected of causing genetic defects.

Additional Hazard Information:

Short Term: 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: Adverse effects most commonly reported in clinical use include local irritation, nausea, vomiting, inflammation of the mouth (stomatitis), facial flushing, conjunctivitis of the eye, tearing (lachrymation), loss of hair, and discoloration of skin. Effects on blood and blood-forming organs have also occurred.

EU Indication of danger: Carcinogenic: Category 2
Mutagenic: Category 2

EU Hazard Symbols:



EU Risk Phrases:

R45 - May cause cancer.
R46 - May cause heritable genetic damage.
Hazardous Substance. Non-Dangerous Goods.

Australian Hazard Classification (NOHSC):

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2. HAZARDS IDENTIFICATION

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	%
Epirubicin Hydrochloride	56390-09-1	260-145-2	Xn;R22 Repr.Cat.2;R60-61 Muta.Cat.2;R46 Carc.Cat.2;R45	0.2

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

Additional Information: 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.

Hazardous Combustion Products: May emit toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, hydrogen chloride, and other chlorine-containing compounds.

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.

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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:	Absorb spills with non-combustible absorbent material and transfer into a labeled container for disposal.
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). Wash thoroughly after handling. 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 as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Epirubicin Hydrochloride Pfizer OEL TWA-8 Hr:	0.6 µg/m ³
Sodium chloride Latvia OEL - TWA	5 mg/m ³
Lithuania OEL - TWA	5 mg/m ³

Analytical Method:	Analytical method available for epirubicin. 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. It is recommended that all operations be fully enclosed and no air recirculated.
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.

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9. PHYSICAL AND CHEMICAL PROPERTIES

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

10. STABILITY AND REACTIVITY

Chemical Stability: Stable under normal conditions of use.
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

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)

Sodium chloride

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

Epirubicin Hydrochloride

Rat Oral LD 50 1350 mg/kg
Rat Para-periosteal LD50 17 mg/kg
Mouse Oral LD50 > 2000 mg/kg
Mouse Intravenous LD50 31.5 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.

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

Sodium chloride

Eye Irritation Rabbit Moderate
Skin Irritation Rabbit Mild

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

Epirubicin Hydrochloride

6 Week(s) Rabbit Intravenous 1 mg/kg/day LOAEL Heart, Kidney
6 Week(s) Dog Intravenous 0.4 mg/kg/day LOAEL Kidney

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

Epirubicin Hydrochloride

Reproductive & Fertility	Rat	Oral	0.3 mg/kg/day	LOAEL	Fertility
Reproductive & Fertility	Rat	Oral	0.1 mg/kg/day	NOAEL	Fertility
Embryo / Fetal Development	Rat	Intravenous	0.8 mg/kg/day	LOAEL	Fetotoxicity
Embryo / Fetal Development	Rat	Intravenous	2 mg/kg/day	LOAEL	Teratogenic, Fetotoxicity
Embryo / Fetal Development	Rat	Intravenous	0.2 mg/kg/day	NOAEL	Teratogenic, Fetotoxicity

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11. TOXICOLOGICAL INFORMATION

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

Epirubicin Hydrochloride

Bacterial Mutagenicity (Ames)	Positive
Mammalian Cell Mutagenicity	HGPRT Positive
Chromosome Aberration	Human Lymphocytes Positive
Chromosome Aberration	Mouse Lymphoma Positive

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Epirubicin Hydrochloride

1 Year(s)	Rat	Intravenous	3.6 mg/kg	LOAEL	Tumors, Female reproductive system
18 Month(s)	Rat	Intravenous	0.5 mg/kg	LOAEL	Tumors

Carcinogen Status: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

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:	Carcinogenic: Category 2 Mutagenic: Category 2

EU Risk Phrases:	R45 - May cause cancer. R46 - May cause heritable genetic damage.
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15. REGULATORY INFORMATION

EU Safety Phrases:

S22 - Do not breathe dust.
S53 - Avoid exposure - obtain special instructions before use.
S36/37 - Wear suitable protective clothing and gloves.

OSHA Label:

WARNING

Suspected of causing cancer.

Suspected of causing genetic defects.

Canada - WHMIS: Classifications

WHMIS hazard class:

D2a - very toxic materials



Epirubicin Hydrochloride

EU EINECS/ELINCS List 260-145-2

Sodium chloride

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

Australia (AICS): Present

EU EINECS/ELINCS List 231-598-3

Water for injection

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

Australia (AICS): Present

REACH - Annex IV - Exemptions from the Present

obligations of Register:

EU EINECS/ELINCS List 231-791-2

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R22 - Harmful if swallowed.

R45 - May cause cancer.

R46 - May cause heritable genetic damage.

R60 - May impair fertility.

R61 - May cause harm to the unborn child.

Data Sources:

Publicly available toxicity information. Pfizer proprietary drug development information.

Reasons for Revision:

Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 15 - Regulatory Information.

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Prepared by:

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

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End of Safety Data Sheet