



MATERIAL SAFETY DATA SHEET

Revision date: 18-Mar-2005

Version: 2.0

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

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017

Emergency telephone number: 1-212-573-2222
Hours of Operation - 24 Hours

Material Name: Epirubicin Hydrochloride Injection

Trade Name: Ellence, Pharmorubicin
Synonyms: None
Chemical Family: Anthracycline
Intended Use: Antineoplastic

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Epirubicin Hydrochloride	56390-09-1	260-145-2	0.2
Sodium chloride	7647-14-5	231-598-3	Proprietary

Ingredient	CAS Number	EU EINECS List	%
Water for Injection	7732-18-5	231-791-2	Proprietary

Additional Information: Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

3. HAZARDS IDENTIFICATION

Appearance: Clear red solution
Signal Word: WARNING

Statement of Known Hazard (GHS Classification):

- POSSIBLE CARCINOGEN

Eye Contact: May cause eye irritation (based on components)

Skin Contact: May cause skin irritation (based on components).

Inhalation: An Occupational Exposure Limit has been established for this substance; see Section 8.

Ingestion: May be harmful if swallowed (based on animal data).

Potential Health Effects: Repeat-dose studies in animals have shown the potential to cause adverse effects on the testes and harm to the developing fetus. Drugs of this class have been associated with rare, but potentially serious cardiac events. These effects have not been observed from occupational exposures, however, those with preexisting cardiovascular illnesses may be at increased risk from exposure. Effects on blood and blood forming organs have also occurred.

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

EU Hazard Symbols:



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R45 - May cause cancer.
R46 - May cause heritable genetic damage.

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.

4. FIRST AID MEASURES

Eye Contact: Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.

Skin Contact: Remove clothing and wash affected skin with soap and water. This material may not be completely removed by conventional laundering. Consult professional laundry service. Do not home launder. If irritation occurs or persists, get medical attention.

Ingestion: Get medical attention. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.

Inhalation: Remove to fresh air. If not breathing, give artificial respiration. Get medical attention.

5. FIRE FIGHTING MEASURES

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

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: Wipe up with a damp cloth and place in container for disposal. 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: Contain the source of the spill or leak if it is safe to do so. Collect spill with a non-combustible absorbent material and transfer to labeled container for disposal.

7. HANDLING AND STORAGE

General Handling: Eliminate possible ignition sources (e.g., heat, sparks, flame, impact, friction, electricity), and follow appropriate grounding and bonding procedures. Avoid contact with eyes, skin and clothing. Avoid breathing vapor or mist. Use with adequate ventilation.

Storage Conditions: Store in a refrigerator. Do not freeze. Protect from light.

Storage Temperature 2 - 8°C (36-46°F)

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Epirubicin Hydrochloride
Pfizer OEL:

0.6 ug/m³

Engineering Controls:

Engineering controls should be used as the primary means to control exposures. Local exhaust ventilation is required unless used in a closed system. For laboratory use, handle in a lab fume hood.

Personal Protective Equipment:

Hands:

Rubber gloves

Eyes:

Safety glasses or goggles

Skin:

Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.

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:

Clear red

Molecular Formula:

Mixture

Molecular Weight:

Mixture

10. STABILITY AND REACTIVITY

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 active ingredient, except where noted.

Acute Toxicity

Epirubicin Hydrochloride

Rat Oral LD 50 1350 mg/kg

Rat Inhalation LC 50 > 0.5 mg/l

Rat Intravenous LD 50 14 mg/kg

Mouse Oral LD 50 > 100 mg/kg

Mouse Intravenous LD 50 16 mg/kg

Sodium chloride

Rat Oral LD50 3000 mg/kg

Rabbit Ocular Irritation Moderate

Rabbit Dermal Irritation Mild

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.

Repeated Dose Toxicity

Epirubicin Hydrochloride

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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

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

Genetic Toxicity

Epirubicin Hydrochloride

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

Carcinogenicity

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: Not listed as a carcinogen by IARC, NTP or US OSHA.

12. ECOLOGICAL INFORMATION

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

13. DISPOSAL CONSIDERATIONS

Disposal Procedures: Observe all local and national regulations when disposing of this material.

14. TRANSPORT INFORMATION

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

EU Labeling: T

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

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

EU EINECS List Not Listed
EU ELINCS List: Not Listed

OSHA Label:
WARNING
• POSSIBLE CARCINOGEN

Canada - WHMIS: Classifications

WHMIS hazard class:
D2a - very toxic materials



Epirubicin Hydrochloride	
EU EINECS List	260-145-2
Sodium chloride	
EU EINECS List	231-598-3
Inventory - United States TSCA - Sect. 8(b)	Listed
Water for Injection	
EU EINECS List	231-791-2
Inventory - United States TSCA - Sect. 8(b)	Listed

16. OTHER INFORMATION

Prepared by: Corporate Occupational Toxicology & Hazard Assessment

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.

End of Safety Data Sheet