



MATERIAL SAFETY DATA SHEET

Revision date: 05-Jan-2007

Version: 1.1

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

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Pfizer Pharmaceuticals Group
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Pfizer Ltd
Ramsgate Road
Sandwich, Kent
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Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300

Emergency telephone number:
ChemSafe (24 hours): +44 (0)208 762 8322

Material Name: Daunorubicin Hydrochloride Freeze-dried for Solution for Injection

Trade Name: Daunoblastin
Synonyms: Daunomycin
Chemical Family: Mixture
Intended Use: Pharmaceutical product used as Antineoplastic, antibiotic agent

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Daunorubicin Hydrochloride	23541-50-6	245-723-4	17

Ingredient	CAS Number	EU EINECS List	%
Sodium chloride	7647-14-5	231-598-3	*
Mannitol	69-65-8	200-711-8	*
Water for injection	7732-18-5	231-791-2	*

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

3. HAZARDS IDENTIFICATION

Appearance: 2 vials : Dry filled vial with a Clear aqueous solution
Signal Word: WARNING

Statement of Hazard: Harmful if swallowed.
May cause adverse effects on blood forming organs
Suspected of damaging the unborn child.
Suspected of causing cancer.
Suspected of causing genetic defects.
May cause cardiovascular system effects

Additional Hazard Information:

Short Term: Harmful if swallowed (based on animal data) . 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.

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Known Clinical Effects: Effects on blood and blood-forming organs have also occurred. 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.

EU Indication of danger: Harmful
Toxic to reproduction, Category 2
Carcinogenic: Category 3
Mutagenic Category 3

EU Hazard Symbols:



EU Risk Phrases:

R22 - Harmful if swallowed.
R40 - Limited evidence of a carcinogenic effect
R60 - May impair fertility.
R61 - May cause harm to the unborn child.
R68 - Possible risk of irreversible effects.

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. If irritation occurs or persists, get medical attention.

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

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

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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 spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. 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:	Avoid contact with eyes, skin and clothing. Avoid breathing dust. Avoid generating airborne dust. Use appropriate ventilation. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling.
Storage Conditions:	Store at room temperature in properly labeled containers. Keep away from heat, sparks and flames.
Storage Temperature:	Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Daunorubicin Hydrochloride
Pfizer OEL TWA-8 Hr:

0.1 ug/m³

Analytical Method:	Analytical method available for Daunorubicin hydrochloride. Contact Pfizer Inc for further information.
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.
Personal Protective Equipment:	
Hands:	Chemical protective 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:	Dry-filled vial / Aqueous solution in vial	Color:	White / Colorless
Molecular Formula:	Mixture	Molecular Weight:	Mixture

10. STABILITY AND REACTIVITY

Stability:	Stable under normal conditions of use.
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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)

Daunorubicin Hydrochloride

Rat	Oral	LD 50	336 mg/kg
Rat	Intravenous	LD50	13 mg/kg
Rat	Intraperitoneal	LD50	20 mg/kg
Mouse	Oral	LD50	205 mg/kg
Mouse	Intravenous	LD50	8.6 mg/kg

Mannitol

Rat	Oral	LD 50	13500 mg/kg
Mouse	Oral	LD 50	22 g/kg

Sodium chloride

Rat	Oral	LD50	3000 mg/kg
Mouse	Oral	LD 50	4000 mg/kg

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)

Sodium chloride

10 Day(s)	Rat	Oral	12500 mg/kg	LOAEL	Kidney, Ureter, Bladder
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Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Daunorubicin Hydrochloride

Embryo / Fetal Development	Rabbit	Oral	0.05 mg/kg/day	LOAEL	Teratogenic, Fetotoxicity
Embryo / Fetal Development	Rat	Oral	4 mg/kg/day	LOAEL	Teratogenic
Embryo / Fetal Development	Rabbit	Intravenous	1.5 mg/kg	LOAEL	Fetotoxicity, Fertility

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

Daunorubicin Hydrochloride

Bacterial Mutagenicity (Ames)	<i>Salmonella</i>	Positive
<i>In Vitro</i> Cytogenetics	Human Lymphocytes	Positive
<i>In Vivo</i> Micronucleus	Not applicable	Positive

Carcinogen Status: See below

Daunorubicin Hydrochloride

IARC: 2B - Possibly Carcinogenic to Humans

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12. ECOLOGICAL INFORMATION

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

13. DISPOSAL CONSIDERATIONS

Disposal Procedures: Dispose of waste in accordance with all applicable laws and regulations.

14. TRANSPORT INFORMATION

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

15. REGULATORY INFORMATION

EU Symbol: T
EU Indication of danger: Harmful
Toxic to reproduction, Category 2
Carcinogenic: Category 3
Mutagenic Category 3

EU Risk Phrases:
R22 - Harmful if swallowed.
R40 - Limited evidence of a carcinogenic effect
R60 - May impair fertility.
R61 - May cause harm to the unborn child.
R68 - Possible risk of irreversible effects.

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
Harmful if swallowed.
May cause adverse effects on blood forming organs
Suspected of damaging the unborn child.
Suspected of causing cancer.
Suspected of causing genetic defects.
May cause cardiovascular system effects

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Canada - WHMIS: Classifications

WHMIS hazard class:

Class D, Division 2, Subdivision A



Daunorubicin Hydrochloride

California Proposition 65

Australia (AICS):

EU EINECS List

Listed: Developmental toxicity

Present

245-723-4

Sodium chloride

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

Australia (AICS):

EU EINECS List

Present

Present

231-598-3

Mannitol

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

Australia (AICS):

EU EINECS List

Present

Present

200-711-8

Water for injection

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

Australia (AICS):

EU EINECS List

Present

Present

231-791-2

16. OTHER INFORMATION

Reasons for Revision:

Updated Section 2 - Composition / Information on Ingredients. Updated Section 3 - Hazard Identification. Updated Section 6 - Accidental Release Measures. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 13 - Disposal Considerations.

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