



# MATERIAL SAFETY DATA SHEET

Revision date: 09-Nov-2004

Version: 1.1

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

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**Emergency telephone number:**  
CHEMTREC (24 hours): 1-800-262-8200

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

### Material Name: Edotecarin IV Solution

**Trade Name:** Not determined  
**Synonyms:** Edotecarin Injectable Solution  
**Chemical Family:** Not determined  
**Intended Use:** Antineoplastic

## 2. COMPOSITION/INFORMATION ON INGREDIENTS

Ingredient	CAS Number	EU EINECS List	%
Propylene Glycol	57-55-6	200-338-0	*
Citric Acid	77-92-9	201-069-1	*
Sodium Citrate, Anhydrous	6132-04-3	Not listed	*
Water for Injection	7732-18-5	231-791-2	*
Edotecarin	174402-32-5	Not listed	1

**Additional Information:** \* Proprietary

## 3. HAZARDS IDENTIFICATION

**Appearance:** Yellow-orange solution  
**Signal Word:** WARNING

**Statement of Hazard:** May cause genetic defects.  
May damage fertility or the unborn child.  
Causes damage to blood and blood forming organs gastrointestinal system

**Eye Contact:** No data available

**Skin Contact:** No data available

**Inhalation:** No data available

**Ingestion:** No data available

**Potential Health Effects:** Fever Diarrhea Nausea Vomiting

**Potential Environmental Effects:** None known

**Potential Physical / Chemical Hazards:** Fine particles (such as dust and mists) may fuel fires/explosions.

**Hazards:**

**EU Indication of danger:** T - Toxic

**EU Hazard Symbols:**

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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:** 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.

## 5. FIRE FIGHTING MEASURES

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

**Hazardous Combustion Products:** May include oxides of carbon. May include oxides of nitrogen.

**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:** Use product only in closed system. When handling, use appropriate personal protective equipment (see Section 8). Avoid inhalation and contact with skin, eye, and clothing. Wash thoroughly after handling.

**Storage Conditions:** Store at room temperature in properly labeled containers. Keep away from heat, sparks and flames.

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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**Engineering Controls:** Engineering controls should be used as the primary means to control exposures.

**Personal Protective Equipment:**

**Hands:** Wear impervious gloves if skin contact is possible.  
**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:** Yellow-orange  
**Molecular Formula:** Mixture  
**Molecular Weight:** Mixture  
**Partition Coefficient (n-octanol/water - Log P):** 2.91

## 10. STABILITY AND REACTIVITY

**Stability:** Stable under recommended storage conditions.  
**Conditions to Avoid:** Fine particles (such as dust and mists) may fuel fires/explosions.  
**Incompatible Materials:** No data available

## 11. TOXICOLOGICAL INFORMATION

### Active Drug Substance Toxicity Data

#### Acute toxicity

Species	Route	End Point	Dose (mg/kg)
Mouse	Oral	LD 50	>2000
Mouse	Intravenous	LD 50	218

#### Irritation / Sensitization

Study Type	Species	Result
Skin Irritation	Rabbit	No effect

#### Repeated Dose Toxicity

Duration	Species	Route	Dose (mg/kg/day)	End Point	Target Organ(s)
2 Week(s)	Rat	Intravenous	1	LOAEL	2 Week(s)
Dog	Intravenous	0.1	NOAEL	4 Week(s)	Rat
Intravenous	3	LOAEL	28 Week(s)	Dog	Intravenous
0.3	NOAEL				

#### Reproduction & Developmental Toxicity

Study Type	Species	Route	Dosage (mg/kg/day)	End Point	Effect(s)
Reproductive & Fertility	Rat	Intravenous	0.1	NOAEL	Fertility
Embryo/Fetal Development	Rat	Intravenous	0.1	NOAEL	Maternal toxicity
Embryo/Fetal Development	Rabbit	Intravenous	3	NOAEL	Maternal toxicity

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### Genetic Toxicity

Study Type	Cell Type / Organism	Result
Bacterial Mutagenicity (Ames)	<i>Salmonella</i> , <i>E. coli</i>	Negative
Chromosome Aberration	Positive	Not applicable
Positive		

**Genetic Toxicity Comments:** The *in vivo* micronucleus assay was conducted in mice.  
**Carcinogenicity:** Not available

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

#### **Citric Acid**

Eye Irritation	Rabbit	Severe
Skin Irritation	Rabbit	Mild

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

## 12. ECOLOGICAL INFORMATION

**Environmental Overview:** No acute toxicity to aquatic organisms was exhibited at the maximum water solubility of this material. Environmental properties of the formulation have not been thoroughly investigated.

**Bioaccumulation and Toxicity:** Bioaccumulation and Toxicity:  
**Partition Coefficient** 2.91  
**(n-octanol/water - Log P):**

### Bacterial Inhibition: (Species, Method, End Point, Duration, Result)

**Bacterial Inhibition Comments:** Activated Sludge: non-inhibitory to 9.7 mg/L

## 13. DISPOSAL CONSIDERATIONS

**Disposal Procedures:** The material should be disposed of by incineration in a chemical incinerator in compliance with national and regional requirements. Dispose of waste in accordance with all applicable laws and regulations.

## 14. TRANSPORT INFORMATION

This material is not regulated for transportation / carriage.

## 15. REGULATORY INFORMATION

**EU Labeling:** EU Labeling:  
**EU Indication of danger:** T - Toxic

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

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## EU Safety Phrases:

S53 - Avoid exposure - obtain special instructions before use.  
S36/37 - Wear suitable protective clothing and gloves.

## OSHA Label:

WARNING

May cause genetic defects.

May damage fertility or the unborn child.

Causes damage to blood and blood forming organs gastrointestinal system

## Canada - WHMIS: Classifications

### WHMIS hazard class:

D2a very toxic materials

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### Propylene Glycol

EU EINECS List

200-338-0

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

Listed

### Citric Acid

EU EINECS List

201-069-1

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