



# MATERIAL SAFETY DATA SHEET

Revision date: 15-Dec-2006

Version: 1.1

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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  
1-212-573-2222

**Pfizer Ltd**  
Ramsgate Road  
Sandwich, Kent  
CT13 9NJ  
United Kingdom  
+00 44 (0)1304 616161

Emergency telephone number:  
CHEMTREC (24 hours): 1-800-424-9300

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

### Material Name: Tirilazad Mesylate IV Solution

**Trade Name:** FREEDOX®  
**Chemical Family:** Mixture  
**Intended Use:** Pharmaceutical product for the treatment of neurological disorders

## 2. COMPOSITION/INFORMATION ON INGREDIENTS

### Hazardous

Ingredient	CAS Number	EU EINECS List	%
Tirilazad Mesylate	110101-67-2	Not listed	0.15
Citric acid	77-92-9	201-069-1	*

Ingredient	CAS Number	EU EINECS List	%
Sodium chloride	7647-14-5	231-598-3	*
Water for Injection	7732-18-5	231-791-2	*
Disodium citrate sesquihydrate	144-33-2	205-623-3	*

**Additional Information:** \* Proprietary

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

## 3. HAZARDS IDENTIFICATION

**Appearance:** Clear, colorless to slightly yellow solution

**Statement of Hazard:** Non-hazardous in accordance with international standards for workplace safety.

**Known Clinical Effects:** Clinical use of this drug has caused liver enzyme changes.

**EU Indication of danger:** Not classified

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**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 eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.

**Skin Contact:** Wash exposed area with soap and water, remove contaminated clothing and obtain medical assistance if irritation occurs.

**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:** Emits toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, sulfur oxides and other sulfur-containing compounds.

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

**Fire / Explosion Hazards:** Not applicable

### 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:** Avoid contact with eyes, skin and clothing. Avoid breathing vapor or mist. Wash thoroughly after handling.

**Storage Conditions:** Store as directed by product packaging.

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Tirilazad Mesylate  
Pfizer OEL TWA-8 Hr:

0.7mg/m<sup>3</sup>

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The exposure limit(s) listed for solid components are only relevant if dust or mist may be generated.

**Analytical Method:** Analytical method available for tirilazad mesylate. Contact Pfizer Inc for further information.

**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:** Not required for the normal use of this product. Wear safety glasses or goggles if eye contact is possible.  
**Skin:** Not required for the normal use of this product. Wear protective clothing when working with large quantities.  
**Respiratory protection:** Not required for the normal use of this product. 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:

<b>Physical State:</b>	Liquid	<b>Color:</b>	Colorless to slightly yellow
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture

### 10. STABILITY AND REACTIVITY

**Stability:** Stable  
**Conditions to Avoid:** None known  
**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)**

**Tirilazad Mesylate**

Rat Intravenous LD 50 179 mg/kg  
Rat Oral LD 50 > 5,000 mg/kg  
Mouse Oral LD 50 > 5000 mg/kg

**Citric acid**

Rat Oral LD50 3000 mg/kg

**Sodium chloride**

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

**Tirilazad Mesylate**

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Eye Irritation Rabbit Severe  
Skin Irritation Rabbit Moderate

### Citric acid

Eye Irritation Rabbit Severe  
Skin Irritation Rabbit Mild

### Sodium chloride

Eye Irritation Rabbit Moderate  
Skin Irritation Rabbit Mild

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

#### Tirilazad Mesylate

30 Day(s) Rat Oral 20 mg/kg/day NOAEL Liver, Thyroid, Gastrointestinal System, Lymphatic system, Lungs, Endocrine system

30 Day(s) Non-human Primate Intravenous 60 mg/kg/day NOEL None identified

#### Sodium chloride

10 Day(s) Rat Oral 12500 mg/kg LOAEL Kidney, Ureter, Bladder

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

#### Tirilazad Mesylate

Reproductive & Fertility Rat Oral 400 mg/kg/day NOAEL Maternal toxicity

Embryo / Fetal Development Rat Oral 800 mg/kg/day NOAEL Fetotoxicity

Embryo / Fetal Development Rabbit Oral 200 mg/kg/day NOAEL Developmental toxicity, Not Teratogenic

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

#### Tirilazad Mesylate

Bacterial Mutagenicity (Ames) *Salmonella* Negative

*In Vitro* Unscheduled DNA Synthesis Rat Negative

Mammalian Cell Mutagenicity Chinese Hamster Ovary (CHO) cells Negative

Micronucleus Mouse Negative

**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 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

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

## 15. REGULATORY INFORMATION

EU Indication of danger: Not classified

### OSHA Label:

Non-hazardous in accordance with international standards for workplace safety.

### Canada - WHMIS: Classifications

#### WHMIS hazard class:

None required

This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all of the information required by the CPR.

#### Sodium chloride

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	231-598-3

#### Water for Injection

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	231-791-2

#### Citric acid

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	201-069-1

#### Disodium citrate sesquihydrate

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	205-623-3

## 16. OTHER INFORMATION

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**Reasons for Revision:**

Updated Section 3 - Hazard Identification. Updated Section 5 - Fire Fighting Measures.  
Updated Section 6 - Accidental Release Measures. Updated Section 8 - Exposure Controls /  
Personal Protection. Updated Section 10 - Stability and Reactivity. 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**