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

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

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS List</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tirilazad Mesylate</td>
<td>110101-67-2</td>
<td>Not listed</td>
<td>0.15</td>
</tr>
<tr>
<td>Citric acid</td>
<td>77-92-9</td>
<td>201-069-1</td>
<td>*</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS List</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium chloride</td>
<td>7647-14-5</td>
<td>231-598-3</td>
<td>*</td>
</tr>
<tr>
<td>Water for Injection</td>
<td>7732-18-5</td>
<td>231-791-2</td>
<td>*</td>
</tr>
</tbody>
</table>
| 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
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/m³
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:

<table>
<thead>
<tr>
<th>Physical State</th>
<th>Color</th>
</tr>
</thead>
<tbody>
<tr>
<td>Liquid</td>
<td>Colorless to slightly yellow</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Molecular Formula</th>
<th>Molecular Weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mixture</td>
<td>Mixture</td>
</tr>
</tbody>
</table>

### 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**
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**
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
MATERIAL SAFETY DATA SHEET

Material Name: Tirilazad Mesylate IV Solution
Revision date: 15-Dec-2006
Prepared by: Corporate Occupational Toxicology & Hazard Assessment

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.

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