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

Pfizer Inc  
Pfizer Pharmaceuticals Group  
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New York, New York 10017  
1-212-573-2222

Pfizer Ltd  
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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: Tirilazad Mesylate IV Concentrate

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

2. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Hazardous</th>
<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>2.5</td>
<td></td>
</tr>
<tr>
<td>Citric acid</td>
<td>77-92-9</td>
<td>201-069-1</td>
<td>*</td>
<td></td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>57-55-6</td>
<td>200-338-0</td>
<td>*</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Additional Information:</th>
<th>* Proprietary</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.</td>
<td></td>
</tr>
</tbody>
</table>

3. HAZARDS IDENTIFICATION

Appearance: Yellow liquid
Signal Word: WARNING

Statement of Hazard: Causes eye irritation.
Causes skin irritation.

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

EU Indication of danger: Irritant

EU Hazard Symbols:
EU Risk Phrases: R36 - Irritating to eyes.

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

Propylene glycol
  Australia TWA
    = 10 mg/m³ TWA
    = 150 ppm TWA
    = 474 mg/m³ TWA

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


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:

Physical State: Liquid
Molecular Formula: Mixture
Color: Yellow
Molecular Weight: Mixture
pH: 2.9

10. STABILITY AND REACTIVITY

Stability: Stable
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)

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
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

**Propylene glycol**
- Skin Irritation: Rabbit, Mild
- Eye 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

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

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

15. REGULATORY INFORMATION

EU Symbol: Xi
EU Indication of danger: Irritant

EU Risk Phrases: R36 - Irritating to eyes.

EU Safety Phrases: S25 - Avoid contact with eyes.
S26 - In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

OSHA Label:
WARNING
Causes eye irritation.
Causes skin irritation.

Canada - WHMIS: Classifications

WHMIS hazard class:
Class D, Division 2, Subdivision B

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

Propylene glycol
16. OTHER INFORMATION

Reasons for Revision: Updated Section 2 - Composition / Information on Ingredients. 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