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: Draxxin (Tulathromycin) solution for injection

Trade Name: Draxxin  
Synonyms: Tulathromycin injectable solution  
Chemical Family: Mixture  
Intended Use: Pharmaceutical product used as antibiotic agent

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>Tulathromycin</td>
<td>217500-96-4</td>
<td>Not listed</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>Monothioglycerol</td>
<td>96-27-5</td>
<td>202-495-0</td>
<td>*</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>Hydrogen chloride</td>
<td>7647-01-0</td>
<td>231-595-7</td>
<td>**</td>
<td></td>
</tr>
<tr>
<td>Sodium hydroxide</td>
<td>1310-73-2</td>
<td>215-185-5</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>
<tr>
<td>Water</td>
<td>7732-18-5</td>
<td>231-791-2</td>
<td>*</td>
<td></td>
</tr>
</tbody>
</table>

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

3. HAZARDS IDENTIFICATION

Appearance: Clear, colorless to slightly yellow solution in multiple-dose vials

Signal Word: WARNING

Statement of Hazard: May cause eye irritation

May cause allergic skin reaction.

Additional Hazard Information:  
Short Term: May cause eye and skin irritation (based on components). May cause allergic reaction (based on animal data). Individuals sensitive to this chemical or other materials in its chemical class may develop allergic reactions. Accidental ingestion may cause effects similar to those seen in clinical use.
**Known Clinical Effects:**
Ingestion of this material may cause effects similar to those generally seen in clinical use of antibiotics including gastrointestinal irritation, vomiting, transient diarrhea, nausea, and abdominal pain.

**EU Indication of danger:**
Irritant

**EU Hazard Symbols:**

**EU Risk Phrases:**
R43 - May cause sensitization by skin contact.

**Note:**
This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients 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. Get medical attention.

**Skin Contact:**
Remove clothing and wash affected skin with soap and water. This material may not be completely removed by conventional laundering. Consult professional laundry service. Do not home launder. If irritation occurs or persists, get medical attention.

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

**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:**
May emit toxic fumes of oxides of carbon and nitrogen.

**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: Use appropriate ventilation. Avoid breathing dust, vapor or mist. Avoid contact with eyes, skin and clothing.

Storage Conditions: Keep container tightly closed when not in use.

Storage Temperature: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Tulathromycin
Pfizer OEL TWA-8 Hr: 1 mg/m³, Sensitizer

Hydrogen chloride
ACGIH Ceiling Threshold Limit: 2 ppm Ceiling
Australia PEAK = 5 ppm Peak
= 7.5 mg/m³ Peak

Sodium hydroxide
OSHA - Final PELS - TWAs: 2 mg/m³
ACGIH Ceiling Threshold Limit: = 2 mg/m³ Ceiling
Australia PEAK = 2 mg/m³ Peak

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. Local and general ventilation should be used as necessary, when handling this material in bulk.

Personal Protective Equipment:

Hands: Wear two layers of disposable gloves.
Eyes: Safety glasses or goggles
Skin: Protective coveralls should be worn. The sleeves should either be taped or have gloves worn over them to prevent material from contacting the skin.
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 in multiple-dose vials
Molecular Formula: Mixture
Color: Colorless to slightly yellow
Molecular Weight: Mixture
pH: 5.4
10. STABILITY AND REACTIVITY

Stability: Stable
Conditions to Avoid: None known
Incompatible Materials: No data available
Hazardous Decomposition Products: No data available
Polymerization: Will not occur

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)

Citric acid
Rat  Oral  LD50  3000 mg/kg

Propylene glycol
Mouse  Oral  LD50  22,000 mg/kg
Rat  Oral  LD50  20,000 mg/kg
Rabbit  Dermal  LD50  20,800 mg/kg

Tulathromycin
Rat  Oral  LDmin. > 2000 mg/kg
Rabbit  Dermal  LD50 > 2000 mg/kg

Hydrogen chloride
Rat  Inhalation  LC50 1H  3,124 ppm
Mouse  Inhalation  LC50 1H  1,108 ppm
Mouse  Oral  LD50  900 mg/kg

Sodium hydroxide
Mouse  IP  LD50  40 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)

Citric acid
Eye Irritation  Rabbit  Severe
Skin Irritation  Rabbit  Mild

Propylene glycol
Skin Irritation  Rabbit  Mild
Eye Irritation  Rabbit  Mild

Tulathromycin
Skin Irritation  Rabbit  Non-irritating
Eye Irritation  Rabbit  Positive
Skin Sensitization - GPMT  Guinea Pig  Severe

Sodium hydroxide
Eye Irritation  Rabbit  Severe
Skin Irritation  Rabbit  Severe
Material Name: Draxxin (Tulathromycin) solution for injection  
Revision date: 02-Jan-2007

12. ECOLOGICAL INFORMATION

Environmental Overview: Based on the concentration of the active ingredient in the formulation, No harmful effects to aquatic organisms are expected.

Bioaccumulation and Toxicity: The active ingredient was not acutely toxic to aquatic organisms at its maximum solubility. See aquatic toxicity data, below.

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

Tulathromycin
- *Daphnia Magna* OECD EC50 1 hr Hours > 20 mg/L
- Mysis Shrimp OECD LC50 48 Hours > 20 mg/L
- Sheepshead Minnow OECD LC50 48 Hours > 20 mg/L
- Red Algae OECD IC50 168 Hours > 20 mg/L

Aquatic Toxicity Comments: A greater than (>) symbol indicates that acute ecotoxicity was not observed at the maximum solubility. Since the substance is insoluble in aqueous solutions above this concentration, an acute ecotoxicity value (i.e. LC/EC50) is not achievable.

Bacterial Inhibition: (Species, Method, End Point, Duration, Result)
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: R43 - May cause sensitization by skin contact.
EU Safety Phrases: S24/25 - Avoid contact with eyes and skin.
S37 - Wear suitable gloves.

OSHA Label:
WARNING
May cause eye irritation
May cause allergic skin reaction.

Canada - WHMIS: Classifications

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

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

Monothioglycerol
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
16. OTHER INFORMATION

Reasons for Revision: Updated Section 2 - Composition / Information on Ingredients. 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 13 - Disposal Considerations.

Prepared by: Toxicology and Hazard Communication
               Pfizer Global Environment, Health, and Safety

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End of Safety Data Sheet