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

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Torisel Injection</th>
</tr>
</thead>
<tbody>
<tr>
<td>Common Name</td>
<td>Not available</td>
</tr>
<tr>
<td>Chemical Name</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Synonyms</td>
<td>Not available</td>
</tr>
<tr>
<td>Product Use</td>
<td>Pharmaceutical product</td>
</tr>
<tr>
<td>Classification</td>
<td>Cytostatic Agent, Anti-Inflammatory Agent</td>
</tr>
</tbody>
</table>

Supplier

Wyeth
P.O. Box 8299
Philadelphia, PA 19101 USA.
Telephone: 1-610-688-4400

Contact E-Mail: pfizer-MSDS@pfizer.com

Emergency Telephone Number

Chemtrec USA, Puerto Rico, Canada 1-800-424-9300
Chemtrec International 1-703-527-3887

2. HAZARDS IDENTIFICATION

<table>
<thead>
<tr>
<th>Emergency Overview</th>
<th>This contains an active pharmaceutical ingredient that can affect body functions; handle with caution.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>Pharmaceutical Liquid</td>
</tr>
<tr>
<td>Physical State</td>
<td>Liquid</td>
</tr>
<tr>
<td>Odor</td>
<td>Slight Alcohol odor</td>
</tr>
</tbody>
</table>

Potential Physical Hazards

| Flammable liquid |

Potential Health Effects

<table>
<thead>
<tr>
<th>Eyes</th>
<th>Irritating to eyes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin</td>
<td>Prolonged skin contact may defat the skin and produce dermatitis</td>
</tr>
<tr>
<td>Inhalation</td>
<td>May cause mucous membrane and upper respiratory tract irritation</td>
</tr>
<tr>
<td>Ingestion</td>
<td>Not available</td>
</tr>
<tr>
<td>Other</td>
<td>The most common effects may include anemia, weakness, hyperglycemia, shortness of breath, hypophosphatemia, headache, diarrhea, vomiting, dizziness, Herpes simplex, rash, drowsiness, taste perversion, mouth sores, nausea, irritation, difficulty breathing, symptoms of drunkeness, sore throat and urticaria.</td>
</tr>
<tr>
<td></td>
<td>Possible development of immunosuppression.</td>
</tr>
<tr>
<td></td>
<td>May impair fertility. May cause harm to the unborn child.</td>
</tr>
</tbody>
</table>

Therapeutic Target Organ(s)

Systemic

| Ethanol listed by NTP and IARC. |

Potential Environmental Effects

See Section 12
3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Common Name</th>
<th>CAS-No</th>
<th>EC No.</th>
<th>Composition</th>
<th>Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Temsirolimus</td>
<td>162635-04-3</td>
<td>Not Applicable</td>
<td>25 mg/ml</td>
<td>N/A</td>
</tr>
<tr>
<td>Propylene Glycol</td>
<td>57-55-6</td>
<td>200-338-0</td>
<td>56-60%</td>
<td>R37, S36</td>
</tr>
<tr>
<td>Ethanol</td>
<td>64-17-5</td>
<td>200-578-6</td>
<td>39.45%</td>
<td>R10, R38, S37</td>
</tr>
<tr>
<td>dl-a-Tocopherol</td>
<td>59-02-9</td>
<td>200-412-2</td>
<td>&lt; 1%</td>
<td>R36, S39</td>
</tr>
</tbody>
</table>

4. FIRST AID MEASURES

Eye Contact
In the case of contact with eyes, rinse immediately with plenty of water for 15 minutes and seek medical advice.

Skin Contact
Wash off with soap and plenty of water

Inhalation
Artificial respiration and/or oxygen may be necessary

Ingestion
Immediate medical attention is required

Other
Participate in a medical surveillance program if working directly with this product

5. FIRE-FIGHTING MEASURES

Flammable Properties
Flammable liquid. Vapors may cause flash fire or explosion.

Extinguishing Media
- Suitable Extinguishing Media: Use water spray, foam, dry chemical or carbon dioxide.
- Unsuitable Extinguishing Media: Do NOT use water jet.

Fire Fighting
Evacuate area and fight fire from a safe distance

Hazardous Combustion Products
Carbon oxides, nitrogen oxides.

Protective Equipment and Precautions for Firefighters
In the event of fire, wear self-contained breathing apparatus and special protective equipment for fire fighters.

Other Information
Flammability Class (OSHA): IA

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions
Safety glasses or goggles when splash potential exists

Environmental Precautions
Local authorities should be advised if a significant spill cannot be contained

Methods for Containment
Not available

Methods for Cleaning up
Take up mechanically and collect in suitable container for disposal
7. HANDLING AND STORAGE

Handling
Restrict access to work area. Avoid breathing vapor or mist. Avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling.

Storage
No special safety precautions required

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Refer to available public information for specific member state Occupational Exposure Limits.

Temsriolimus
Pfizer Occupational Exposure Band (OEB):
OEB5 (control exposure to <1ug/m³)

Ethanol
Exposure Guideline: 1900 mg/m³

Engineering Controls
Engineering controls should be used as the primary means to control exposures. General room ventilations is adequate unless the process generates dusts mists, fumes, or vapors. Keep airborne contamination levels below the exposure limits listed above in this section.

Personal Protective Equipment

Eye/face Protection
Wear safety glasses or goggles if eye contact is possible.

Skin Protection
Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

Respiratory Protection
If airborne exposures are within or exceed the Occupational Exposure Band (OEB) range, wear an appropriate respirator with a protection factor sufficient to control exposures to the bottom of the OEB range.

General Hygiene Considerations
Avoid contact with skin, eyes and clothing Conduct a task-specific risk assessment prior to authorizing work with this product Consult a health and safety professional for specific PPE, respirator and risk assessment guidance

Other
Limit access to only personnel trained in the safe handling of this material

9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>Pharmaceutical Liquid</td>
</tr>
<tr>
<td>Color</td>
<td>Clear</td>
</tr>
<tr>
<td>Odor Threshold</td>
<td>Not available</td>
</tr>
<tr>
<td>pH</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Specific Gravity</td>
<td>0.9237g/ml</td>
</tr>
<tr>
<td>Solubility</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Partition Coefficient</td>
<td>Not available</td>
</tr>
<tr>
<td>(n-octanol/water)</td>
<td></td>
</tr>
<tr>
<td>Boiling Point</td>
<td>93°C</td>
</tr>
<tr>
<td>Flash Point</td>
<td>21.1°C</td>
</tr>
<tr>
<td>Flammability Limits in Air</td>
<td>Upper Not available</td>
</tr>
<tr>
<td>Upper</td>
<td>Not available</td>
</tr>
<tr>
<td>Lower</td>
<td>Not available</td>
</tr>
<tr>
<td>Water Solubility</td>
<td>Poorly soluble</td>
</tr>
<tr>
<td>Evaporation Rate</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Vapor Pressure</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Autoignition Temperature</td>
<td>Not available</td>
</tr>
<tr>
<td>Melting Point</td>
<td>Not available</td>
</tr>
<tr>
<td>Melting Point</td>
<td>Not available</td>
</tr>
<tr>
<td>Melting Point</td>
<td>Not available</td>
</tr>
<tr>
<td>Melting Point</td>
<td>Not available</td>
</tr>
</tbody>
</table>

Revision Date Not applicable
10. STABILITY AND REACTIVITY

**Chemical Stability**
Stable at room temperature.

**Conditions to Avoid**
No data available

**Materials to Avoid**
No materials to be especially mentioned.

**Hazardous Decomposition Products**
None under normal use.

**Possibility of Hazardous Reactions**
None under normal use.

11. TOXICOLOGICAL INFORMATION

**Temsirolimus**

- **LD50 Oral**
  - > 100 mg/kg rats
  - > 100 mg/kg mice

- **Acute Dermal Irritation**: No data available

- **Primary Eye Irritation**: No data available

- **Sensitization**: No data available

**Ethanol**

- **LD50 Oral**
  - 3450 mg/kg mice
  - 7060 mg/kg rats

- **Acute Dermal Irritation**: Moderate irritation effect in rabbits.

- **Primary Eye Irritation**: Severely irritating to rabbit eyes.

- **Sensitization**: Not applicable

**Multiple Dose Toxicity**

**Temsirolimus**

- **No Toxicologic Effect**
- **Dose/Species/Study Length:**
  - The acute and chronic toxicity has been evaluated in mice, rats and monkeys. No compound-related mortality was observed in mice or rats. Compound-related effects observed in rats and monkeys included thymic and/or lymphoid atrophy, blood effects, and changes in male reproductive organs. In rats only, the following compound-related effects were observed: blood effects, hyperglycemia, cataracts, pancreatic effects, bone marrow effects, changes in female reproductive organs, and increased numbers of pulmonary alveolar macrophages. In monkeys only, colitis and chronic diarrhea were observed.

**Ethanol**

- **No Toxicologic Effect**
- **Dose/Species/Study Length:**
  - Repeated contact can dry the skin with cracking, peeling, and itching. Repeated high exposure may affect the liver and nervous system.

**Maximum Tolerated Dose (MTD), Oral**

**Temsirolimus**

- **Carcinogenicity**: No data available
- **Genetic Toxicity**: No evidence of mutagenicity was observed in a battery of in vitro and in vivo assays.
- **Reproductive Toxicity**: Studies were found to adversely affect male, but not female, fertility in rats causing decreased sperm counts, sperm mobility, hypospermia, decreased reproductive organ weights, testicular tubular degeneration, and prostate atrophy.
- **Developmental Toxicity**: Developmental studies in rats and rabbits have shown embryo/fetal mortality, decreased fetal growth and increased incidence of intestinal protrusion through the abdomen in rabbits.
12. ECOLOGICAL INFORMATION

Ethanol
- **Carcinogenicity**: No data available
- **Genetic Toxicity**: May cause genetic changes.
- **Reproductive Toxicity**: See Developmental Toxicity.
- **Developmental Toxicity**: Repeated exposure may cause spontaneous abortions, as well as birth defects and other developmental problems (fetal alcohol syndrome).

Temsirolimus
- **Target Organ(s) of Toxicity**: No data available

Ethanol
- **Target Organ(s) of Toxicity**: No data available

13. DISPOSAL CONSIDERATIONS

Waste Disposal Method
Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.
14. TRANSPORT INFORMATION

Transport Information

Proper Shipping Name: Flammable liquid, n.o.s. (ethanol)
Identification Number: UN 1993
Hazard Class: 3
Packing Group: II
Flashpoint: 21 °C

Exceptions: For small quantities packed in combination packaging [limited to inner packaging <= 1.0L*** and outer packaging <= 30 kg (66 lb.) gross weight], the following will apply. In addition, see "excepted quantity" provisions if applicable.***

Note: If your commodity meets the definition of a limited quantity and is packaged for retail sale, it may be considered a Consumer Commodity and excepted from additional requirements as applicable.

U.S. Department of Transport (DOT)
Proper Shipping Name Consumer Commodity
Hazard Class ORM-D

International Air Transport Association (IATA)
UN-No ID 8000
Proper Shipping Name Consumer Commodity
Hazard Class 9
Packing Group Not Applicable

International Maritime Dangerous Goods (IMDG)
Proper Shipping Name Flammable liquid, n.o.s. (ethanol), Ltd. Qty
Hazard Class 3
UN-No 1993
Packing Group II
Flashpoint: 21 °C

Transport of Dangerous Goods by Road (ADR)
Proper Shipping Name Flammable liquid, n.o.s. (ethanol), Ltd. Qty
Hazard Class 3
UN-No 1993
Packing Group II

15. REGULATORY INFORMATION

According to present data no classification and labeling is required according to Directives 67/548/EEC or 1999/45/EC.

16. OTHER INFORMATION

Prepared By Wyeth Department of Environment, Health & Safety
Format This MSDS was prepared in accordance with Directive 2001/58/EC.
List of References See Patient Package Insert for more information.
Revision Summary Changes to Section 7, 8
Disclaimer:
The information, data, recommendations, and suggestions appearing in this material safety data sheet (MSDS) and/or in materials regarding our active pharmaceutical ingredients (APIs) or products are based upon tests and data believed to be reliable as of the date of publication. NO REPRESENTATIONS OR WARRANTIES, EITHER EXPRESSED OR IMPLIED, INCLUDING WITHOUT LIMITATION ANY WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, OR ANY OTHER WARRANTY IS MADE WITH REGARD TO THE INFORMATION PROVIDED IN THE MSDS, REGARDING THE API, OR THE PRODUCT TO WHICH THE INFORMATION PERTAINS. Accordingly, Wyeth will not be responsible for any damages resulting from use of, or reliance upon, this information as conditions of use are beyond our control. Users are responsible for assuring the safety of their workers and safe operating conditions, and for determining whether the API or product is suitable for their particular purposes. Users shall assume all risks of their use, handling, and disposal of the API and/or product in accordance with all appropriate and applicable regulations. This information relates only to the API or product designated herein, and does not relate to its use in combination with any other API, material, product, or process. No permission is granted for the use of any API or product in a manner that might infringe on existing patents.

End of MSDS