1. PRODUCT AND COMPANY IDENTIFICATION

Product Name: Torisel----Finished and Packaged Product
Common Name: Not available
Chemical Name: Not applicable
Synonyms: Temsirolimus, CCI-779, Torisel
Product Use: Pharmaceutical product
Classification: Cytostatic Agent Anti-Inflammatory Agent

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

Emergency Telephone Number: Chemtrec USA, Puerto Rico, Canada 1-800-424-9300
Chemtrec International 1-703-527-3887

2. HAZARDS IDENTIFICATION

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 drunkenness sore throat and urticaria</td>
</tr>
</tbody>
</table>

Possible development of immunosuppression.

May impair fertility May cause harm to the unborn child.

Please see Patient Package Insert for further information.

Therapeutic Target Organ(s): Systemic

Ethanol listed by NTP and IARC

Potential Environmental Effects: See Section 12

Preparation Date: 21-Nov-2008
Revision Date: 22-Jan-2010
Revision Number: 1.1**
3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Common Name</th>
<th>CAS-No</th>
<th>Composition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Temsirolimus</td>
<td>162635-04-3</td>
<td>25 mg/ml</td>
</tr>
<tr>
<td>Propylene Glycol</td>
<td>57-55-6</td>
<td>56-60%</td>
</tr>
<tr>
<td>Ethanol</td>
<td>64-17-5</td>
<td>39.45%</td>
</tr>
<tr>
<td>dl-a-Tocopherol</td>
<td>59-02-9</td>
<td>1% &lt;</td>
</tr>
</tbody>
</table>

4. FIRST AID MEASURES

Eye Contact: In 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 not 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, alcohol-resistant foam, dry chemical or carbon dioxide.

Unsuitable Extinguishing Media: Do not use a solid water stream as it may scatter and spread fire.

Fire Fighting: Evacuate area and fight fire from a safe distance.

Hazardous Combustion Products: Hazardous Combustion Products.

Protective Equipment and Precautions for Firefighters: As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

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
Keep container tightly closed

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Temsirolimus

Pfizer Occupational Exposure Band (OEB):

OEB5 (control exposure to <1ug/m³)

Ethanol

Exposure Guideline: 1900 mg/m³

Engineering Controls

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>Odor Threshold</td>
<td>Not available</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>0.9237 g/ml</td>
</tr>
<tr>
<td>Solubility</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Partition Coefficient</td>
<td>Not available</td>
</tr>
<tr>
<td>Physical State</td>
<td>Liquid</td>
</tr>
<tr>
<td>Odor</td>
<td>Slight Alcohol odor</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>
</tbody>
</table>
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**

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>LD50 Oral</td>
<td>&gt; 100 mg/kg rats</td>
</tr>
<tr>
<td>LD50 Oral</td>
<td>&gt; 100 mg/kg mice</td>
</tr>
<tr>
<td>Acute Dermal Irritation</td>
<td>No data available</td>
</tr>
<tr>
<td>Primary Eye Irritation</td>
<td>No data available</td>
</tr>
<tr>
<td>Sensitization</td>
<td>No data available</td>
</tr>
</tbody>
</table>

**Ethanol**

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>LD50 Oral</td>
<td>3450 mg/kg mice</td>
</tr>
<tr>
<td>LD50 Oral</td>
<td>7060 mg/kg rats</td>
</tr>
<tr>
<td>Acute Dermal Irritation</td>
<td>Moderate irritation effect in rabbits.</td>
</tr>
<tr>
<td>Primary Eye Irritation</td>
<td>Severely irritating to rabbit eyes.</td>
</tr>
<tr>
<td>Sensitization</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>

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.
12. ECOLOGICAL INFORMATION

The following effects are based on the Active Pharmaceutical Ingredient.

Chemical Fate Information

<table>
<thead>
<tr>
<th>Temsirolimus</th>
<th>Not available</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mobility</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>Biodegradability</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>Stability in Water</strong></td>
<td>Slowly hydrolyzes at neutral pH, with an increasing rate as pH increases.</td>
</tr>
<tr>
<td><strong>Bioaccumulation</strong></td>
<td>Not available</td>
</tr>
</tbody>
</table>

Ecotoxicity

<table>
<thead>
<tr>
<th>Temsirolimus</th>
<th>Not available</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Microorganisms</strong></td>
<td>EC50 &gt; Aqueous solubility limit</td>
</tr>
<tr>
<td><strong>Algae</strong></td>
<td>EC50/72h/algae = 0.063 mg/l, NOEC = 0.015 mg/l</td>
</tr>
<tr>
<td><strong>Daphnia</strong></td>
<td>EC50/48h/daphnia &gt; Aqueous solubility limit</td>
</tr>
<tr>
<td><strong>Fish</strong></td>
<td>LC50/96h/Fathead minnows &gt; Aqueous solubility limit</td>
</tr>
</tbody>
</table>
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

This material is regulated for transportation as a hazardous material/dangerous goods.

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)
Proper Shipping Name: Consumer Commodity
Hazard Class: 9
UN-No: ID 8000
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: UN 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: UN 1993
Packing Group: II

15. REGULATORY INFORMATION

USA

Federal Regulations
OSHA Regulatory Status
This material is not considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200)

SARA 313
Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40n of the Code of Federal Regulations, Part 372.

SARA 311/312 Hazardous Categorization
Acute Health Hazard No
Chronic Health Hazard No
Fire Hazard No
Sudden Release of Pressure Hazard No
Reactive Hazard No

This product does not contain any HAPs.

State Regulations
California Proposition 65
Ethyl alcohol (ethanol) is listed.

Canada
Not classified

WHMIS Hazard Class
Non-controlled

European Union
In accordance with EC directives or respective national laws, the product does not need to be classified nor labeled.

16. OTHER INFORMATION

Prepared By Wyeth Department of Environment, Health & Safety
Format This MSDS was prepared in accordance with ANSI Z400.1-2004.
List of References See Patient Package Insert for more information.
Revision Summary Changes to Section 7, 8, 14

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