

### Torisel Injection

Preparation Date 28-Mar-2007

Revision Date 29-Jun-2007

Revision Number 1

## 1. PRODUCT AND COMPANY IDENTIFICATION

**Product Name** Torisel Injection  
**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

### Emergency Overview

This contains an active pharmaceutical ingredient that can affect body functions; handle with caution.

**Appearance** Pharmaceutical Liquid      **Physical State** Liquid      **Odor** Slight alcohol odor

**Potential Physical Hazards** Flammable liquid

### Potential Health Effects

**Eyes** Irritating to eyes  
**Skin** Prolonged skin contact may defat the skin and produce dermatitis  
**Inhalation** May cause mucous membrane and upper respiratory tract irritation  
**Ingestion** Not available  
**Other** 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.

Possible development of immunosuppression.

May impair fertility. May cause harm to the unborn child.

Please see Patient Package Insert for further information.  
Systemic

### Therapeutic Target Organ(s)

Not listed by OSHA, NTP or IARC. Ethanol listed by NTP and IARC.

**Potential Environmental Effects** See Section 12

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Common Name	CAS-No	Composition
Temsirolimus	162635-04-3	25 mg/ml
Propylene Glycol	57-55-6	56-60%
Ethanol	64-17-5	39.45%
dl-a-Tocopherol	59-02-9	< 1%

### 4. FIRST AID MEASURES

<b>Eye Contact</b>	In the case of contact with eyes, rinse immediately with plenty of water for 15 minutes and seek medical advice.
<b>Skin Contact</b>	Take off contaminated clothing and shoes immediately. Wash off immediately with soap and plenty of water. If skin irritation persists, call a physician.
<b>Inhalation</b>	Move to fresh air. Artificial respiration and/or oxygen may be necessary. If symptoms persist, call a physician.
<b>Ingestion</b>	If symptoms persist, call a physician. Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person.
<b>Other</b>	Participate in a medical surveillance program if working directly with this product

### 5. FIRE-FIGHTING MEASURES

<b>Flammable Properties</b>	Flammable liquid. Vapors may cause flash fire or explosion..
<b>Extinguishing Media</b>	
<b>Suitable Extinguishing Media</b>	Use water spray, foam, dry chemical or carbon dioxide.
<b>Unsuitable Extinguishing Media</b>	Do NOT use water jet.
<b>Fire Fighting</b>	Evacuate area and fight fire from a safe distance. Cool closed containers exposed to fire with water spray. In the event of fire and/or explosion do not breathe fumes.
<b>Hazardous Combustion Products</b>	Carbon oxides, nitrogen oxides.
<b>Protective Equipment and Precautions for Firefighters</b>	In the event of fire, wear self-contained breathing apparatus and special protective equipment for fire fighters.
<b>Other Information</b>	Flammability Class (OSHA): IA

### 6. ACCIDENTAL RELEASE MEASURES

<b>Personal Precautions</b>	Refer to protective measures listed in Sections 7 and 8.
<b>Environmental Precautions</b>	Prevent product from entering drains. Local authorities should be advised if a significant spill cannot be contained.
<b>Methods for Containment</b>	Not available
<b>Methods for Cleaning up</b>	Take up mechanically and collect in suitable container for disposal. Clean contaminated surface thoroughly. Avoid formation of dust and aerosols.

## 7. HANDLING AND STORAGE

<b>Handling</b>	For personal protection see Section 8 Handle in accordance with good industrial hygiene and safety practice Skin should be washed after contact.  Take precautionary measures against static discharges Keep away from open flames, hot surfaces and sources of ignition When processing, use electrically classified equipment.
<b>Storage</b>	No special safety precautions required. Keep container tightly closed.

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<b>Common Name</b> Temsirolimus Ethanol	<b>Exposure Guideline</b> 0.1 mcg/m <sup>3</sup> 1900 mg/m <sup>3</sup>
<b>Engineering Controls</b>	Apply technical measures to comply with the occupational exposure guideline. Local exhaust ventilation is needed for limited open handling or where aerosols may be generated.
<b>Personal Protective Equipment</b>	
<b>Eye/face Protection</b>	Wear safety glasses with side-shields
<b>Skin Protection</b>	Wear double gloves or "chemotherapy" gloves Immediately change gloves when torn, punctured, or contaminated Wear closed-front, low-permeability protective gowns with tight-fitting wrist cuffs when working with this product
<b>Respiratory Protection</b>	Base respirator selection on a risk assessment.
<b>General Hygiene Considerations</b>	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
<b>Other</b>	Limit access to only personnel trained in the safe handling of this material

## 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Appearance</b>	Pharmaceutical Liquid	<b>Physical State</b>	Liquid
<b>Color</b>	Clear	<b>Odor</b>	Slight alcohol odor
<b>Odor Threshold</b>	Not available		
<b>pH</b>	Not applicable		
<b>Specific Gravity</b>	0.9237g/ml	<b>Water Solubility</b>	Poorly soluble
<b>Solubility</b>	Not applicable	<b>Evaporation Rate</b>	Not applicable
<b>Partition Coefficient (n-octanol/water)</b>	Not available	<b>Vapor Pressure</b>	Not applicable
<b>Boiling Point</b>	Not applicable	<b>Autoignition Temperature</b>	Not available
<b>Flash Point</b>	21.1°C /70°F	<b>Method</b>	None
<b>Melting Point</b>	Not available		
<b>Flammability Limits in Air</b>	<b>Upper</b> Not available	<b>Lower</b>	Not available
<b>Explosion Limits</b>	<b>Upper</b> Not available	<b>Lower</b>	Not available

## 10. STABILITY AND REACTIVITY

<b>Chemical Stability</b>	Stable at room temperature.
<b>Conditions to Avoid</b>	No data available
<b>Materials to Avoid</b>	No materials to be especially mentioned.
<b>Hazardous Decomposition Products</b>	None under normal use.
<b>Possibility of Hazardous Reactions</b>	None under normal use.

## 11. TOXICOLOGICAL INFORMATION

The following effects are based on the Active Pharmaceutical Ingredient.

### Acute Toxicity

#### Temsirolimus

<b>LD50 Oral</b>	> 100 mg/kg rats > 100 mg/kg mice
<b>Acute Dermal Irritation</b>	Not available
<b>Primary Eye Irritation</b>	Not available
<b>Sensitization</b>	Not available

#### Ethanol

<b>LD50 Oral</b>	3450 mg/kg mice 7060 mg/kg rats
<b>Acute Dermal Irritation</b>	Moderate irritation effect in rabbits.
<b>Primary Eye Irritation</b>	Severely irritating to rabbit eyes.
<b>Sensitization</b>	Not applicable

### Multiple Dose Toxicity

#### Temsirolimus

<b>No Toxicologic Effect Dose/Species/Study Length:</b>	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.
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#### Ethanol

<b>No Toxicologic Effect Dose/Species/Study Length:</b>	Repeated contact can dry the skin with cracking, peeling, and itching. Repeated high exposure may affect the liver and nervous system.
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### Genetic, Reproductive, Developmental Toxicity

#### Temsirolimus

<b>Carcinogenicity</b>	No studies to assess the carcinogenic potential have been performed.
<b>Genetic Toxicity</b>	No evidence of mutagenicity was observed in a battery of <i>in vitro</i> and <i>in vivo</i> assays.

<b>Reproductive Toxicity</b>	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.
<b>Developmental Toxicity</b>	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.
<b>Ethanol</b>	
<b>Carcinogenicity</b>	No studies to assess the carcinogenic potential have been performed.
<b>Genetic Toxicity</b>	May cause genetic changes.
<b>Reproductive Toxicity</b>	See Developmental Toxicity.
<b>Developmental Toxicity</b>	Repeated exposure may cause spontaneous abortions, as well as birth defects and other developmental problems (fetal alcohol syndrome).

## 12. ECOLOGICAL INFORMATION

The following effects are based on the Active Pharmaceutical Ingredient.

**Chemical Fate Information** Not available

### Temsirolimus

**Mobility** Not available  
**Biodegradability** Not available  
**Stability in Water** Slowly hydrolyzes at neutral pH, with an increasing rate as pH increases.  
**Bioaccumulation** Not available

**Ecotoxicity** Not available

### Temsirolimus

**Microorganisms** EC50 > Aqueous solubility limit  
**Algae** EC50/72h/algae = 0.063 mg/l, NOEC = 0.015 mg/l  
**Daphnia** EC50/48h/daphnia > Aqueous solubility limit  
**Fish** LC50/96h/Fathead minnows > Aqueous solubility limit

## 13. DISPOSAL CONSIDERATIONS

**Waste Disposal Method** Dispose of in accordance with local and national regulations.

## 14. TRANSPORT INFORMATION

**U.S. Department of Transport (DOT)** Not regulated  
**Canadian Transport of Dangerous Goods (TDG)** Not regulated  
**International Air Transport Association (IATA)**  
**Proper Shipping Name** Consumer Commodity  
**Hazard Class** 9  
**UN-No** ID 8000  
**Transport of Dangerous Goods by Rail (RID)** Not regulated  
**Transport of Dangerous Goods by Road (ADR)** Not regulated

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**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**

<b>Acute Health Hazard</b>	No
<b>Chronic Health Hazard</b>	No
<b>Fire Hazard</b>	No
<b>Sudden Release of Pressure Hazard</b>	No
<b>Reactive Hazard</b>	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.

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**16. OTHER INFORMATION**

<b>Prepared By</b>	Wyeth Department of Environment, Health & Safety
<b>Format</b>	This MSDS was prepared in accordance with ANSI Z400.1-2004.
<b>List of References</b>	See Patient Package Insert for more information.
<b>Revision Summary</b>	Change to Torisel Injection

## Disclaimer:

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**End of MSDS**