

Torisel Injection

Preparation Date 28-Mar-2007

Revision Date 22-Jan-2010***

Revision Number 6.1***

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

Product Name Torisel Injection
Common Name Not available
Chemical Name Not applicable
Synonyms Not available
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

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

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.

Therapeutic Target Organ(s)

Please see Patient Package Insert for further information.
Systemic

Ethanol listed by NTP and IARC.

Potential Environmental Effects

See Section 12

3. COMPOSITION/INFORMATION ON INGREDIENTS

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

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.

Temsirolimus Pfizer Occupational Exposure Band (OEB):	OEB5 (control exposure to <1ug/m ³)
Ethanol Exposure Guideline:	1900 mg/m ³
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

Appearance	Pharmaceutical Liquid	Physical State	Liquid
Color	Clear	Odor	Slight Alcohol odor
Odor Threshold	Not available		
pH	Not applicable		
Specific Gravity	0.9237g/ml	Water Solubility	Poorly soluble
Solubility	Not applicable	Evaporation Rate	Not applicable
Partition Coefficient (n-octanol/water)	Not available	Vapor Pressure	Not applicable
Boiling Point	93°C	Autoignition Temperature	Not available
Flash Point	21.1°C	Melting Point	Not available
Flammability Limits in Air	Upper Not available	Lower Not available	
Upper Not available	Lower Not available		

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.
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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.
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Maximum Tolerated Dose (MTD), Oral

Temsirolimus

Carcinogenicity	No data available
Genetic Toxicity	No evidence of mutagenicity was observed in a battery of <i>in vitro</i> and <i>in vivo</i> 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.

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
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Ethanol

Target Organ(s) of Toxicity	No data available
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12. ECOLOGICAL INFORMATION

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 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 This material is classified as hazardous for transport.

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:

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End of MSDS