



SAFETY DATA SHEET

Revision date: 26-Nov-2013

Version: 1.1

Page 1 of 9

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

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Material Name: Torisel Injection

Trade Name:	TORISEL
Synonyms:	Temsirolimus Concentrate for Injection
Chemical Family:	Not determined
Intended Use:	Antineoplastic

2. HAZARDS IDENTIFICATION

Appearance: Clear, colorless to pale yellow liquid
Signal Word: DANGER

Statement of Hazard: Flammable liquid and vapor.
May damage fertility or the unborn child

Additional Hazard Information:
Short Term: Accidental ingestion may cause effects similar to those seen in clinical use.
Long Term: Chronic ingestion of ethanol has been associated with an increased incidence of cancer, liver cirrhosis, and, if ingested during pregnancy, congenital malformations.

Known Clinical Effects: Adverse effects associated with therapeutic use include hypersensitivity reactions, nausea, weakness, skin rash, weight loss inflammation of the mouth (stomatitis), itching sensation (pruritus), decreased white blood cells (leukopenia), decreased red blood cell count (anemia), lung inflammation (pneumonitis), and infection.

EU Classification
EU Indication of danger: Toxic to Reproduction: Category 2
Flammable

EU Hazard Symbols:



EU Risk Phrases:
R10 - Flammable.
R60 - May impair fertility.
R62 - Possible risk of impaired fertility.

SAFETY DATA SHEET

Material Name: Torisel Injection
Revision date: 26-Nov-2013

Page 2 of 9
Version: 1.1

2. HAZARDS IDENTIFICATION

Australian Hazard Classification (NOHSC): Hazardous Substance. Dangerous Goods.

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates 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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Citric acid, anhydrous	77-92-9	201-069-1	Not Listed	*
Ethanol	64-17-5	200-578-6	F; R11	42.7
Propylene glycol	57-55-6	200-338-0	Not Listed	*
Temsirolimus	162635-04-3	Not Listed	Repr. Cat.2;R60-61; N,R50/53	2.7

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
DL-Alpha tocopherol	10191-41-0	233-466-0	Not Listed	*

Additional Information: Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

For the full text of the R phrases mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

5. FIRE FIGHTING MEASURES

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

Fire Fighting Procedures: During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

SAFETY DATA SHEET

Material Name: Torisel Injection
Revision date: 26-Nov-2013

Page 3 of 9
Version: 1.1

Fire / Explosion Hazards: Flammable liquid.

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: Flammable liquid and vapor- keep away from ignition sources and clean up spills promptly. Eliminate possible ignition sources (e.g., heat, sparks, flame, impact, friction, electricity), and follow appropriate grounding and bonding procedures. Avoid contact with eyes, skin, and clothing. Use appropriate personal protective equipment. Wash thoroughly after handling. Minimize generating airborne mists and vapors. Avoid breathing mist or aerosols. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls. Refer to Section 12 - Ecological Information, for information on potential effects on the environment.

Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Ethanol

ACGIH Threshold Limit Value (STEL)	1000 ppm
Australia TWA	1000 ppm
	1880 mg/m ³
Austria OEL - MAKs	1000 ppm
	1900 mg/m ³
Belgium OEL - TWA	1000 ppm
	1907 mg/m ³
Bulgaria OEL - TWA	1000.0 mg/m ³
Czech Republic OEL - TWA	1000 mg/m ³
Denmark OEL - TWA	1000 ppm
	1900 mg/m ³
Estonia OEL - TWA	500 ppm
	1000 mg/m ³
Finland OEL - TWA	1000 ppm
	1900 mg/m ³
France OEL - TWA	1000 ppm
	1900 mg/m ³
Germany - TRGS 900 - TWAs	500 ppm
	960 mg/m ³

SAFETY DATA SHEET

Material Name: Torisel Injection
Revision date: 26-Nov-2013

Page 4 of 9
Version: 1.1

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Germany (DFG) - MAK	500 ppm 960 mg/m ³
Greece OEL - TWA	1000 ppm 1900 mg/m ³
Hungary OEL - TWA	1900 mg/m ³
Latvia OEL - TWA	1000 mg/m ³
Lithuania OEL - TWA	500 ppm 1000 mg/m ³
Netherlands OEL - TWA	260 mg/m ³
OSHA - Final PELs - TWAs:	1000 ppm 1900 mg/m ³
Poland OEL - TWA	1900 mg/m ³
Portugal OEL - TWA	1000 ppm
Romania OEL - TWA	1000 ppm 1900 mg/m ³
Slovakia OEL - TWA	500 ppm 960 mg/m ³
Slovenia OEL - TWA	1000 ppm 1900 mg/m ³
Spain OEL - TWA	1000 ppm 1910 mg/m ³
Sweden OEL - TWAs	500 ppm 1000 mg/m ³
Propylene glycol	
Australia TWA	150 ppm 474 mg/m ³ 10 mg/m ³
Ireland OEL - TWAs	150 ppm 470 mg/m ³ 10 mg/m ³
Latvia OEL - TWA	7 mg/m ³
Lithuania OEL - TWA	7 mg/m ³
Temsirolimus	
Pfizer Occupational Exposure Band (OEB):	OEB 5 (control exposure to <1ug/m ³)
Engineering Controls:	Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.
Environmental Exposure Controls:	Refer to specific Member State legislation for requirements under Community environmental legislation.
Personal Protective Equipment:	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
Hands:	Impervious, disposable gloves (double suggested) are recommended if skin contact with drug product is possible and for bulk processing operations.
Eyes:	Wear safety glasses or goggles if eye contact is possible.
Skin:	Impervious disposable protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.
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.

SAFETY DATA SHEET

Material Name: Torisel Injection
Revision date: 26-Nov-2013

Page 5 of 9
Version: 1.1

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Liquid	Color:	Clear, colorless to pale yellow
Molecular Formula:	Mixture	Molecular Weight:	Mixture
Boiling Point (°C):	93		
Specific Gravity:	0.9237 g/mL		
Flash Point (Liquid) (°C):		21.1	

10. STABILITY AND REACTIVITY

Chemical Stability:	Stable under normal conditions of use.
Conditions to Avoid:	Fine particles (such as dust and mists) may fuel fires/explosions.
Incompatible Materials:	As a precautionary measure, keep away from strong oxidizers

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)

Temsirolimus

Rat Oral Minimum Lethal Dose > 100 mg/kg
Rat IV LD 50 50 mg/kg
Mouse Oral Minimum Lethal Dose > 100 mg/kg
Mouse Intravenous LD 50 > 50 mg/kg

Citric acid, anhydrous

Rat Oral LD50 3000 mg/kg

Ethanol

Mouse Oral LD50 3,450 g/m³
Rat Oral LD50 7,060 mg/kg
Mouse Inhalation LC50 4h 39 g/m³
Rat Inhalation LC50 10h 20,000 ppm

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, anhydrous

Eye Irritation Rabbit Severe
Skin Irritation Rabbit Mild

Ethanol

Eye Irritation Rabbit Severe

SAFETY DATA SHEET

Material Name: Torisel Injection
Revision date: 26-Nov-2013

Page 6 of 9
Version: 1.1

11. TOXICOLOGICAL INFORMATION

Propylene glycol

Skin Irritation Rabbit Mild
Eye Irritation Rabbit Mild

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Temsirolimus

2 Week(s)	Mouse	Oral	10 mg/kg/day	LOAEL	Male reproductive system
3 Month(s)	Mouse	Oral	10 mg/kg/day	LOAEL	Skin
1 Month(s)	Rat	Oral	5 mg/kg/day	LOAEL	Lymphoid tissue, Blood
3 Month(s)	Rat	Oral	0.5 mg/kg/day	LOAEL	Pancreas, Eyes
6 Month(s)	Rat	Oral	0.3 mg/kg/day	NOAEL	None identified

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Temsirolimus

Fertility & Early Embryonic Development - Males	Rat	Oral	0.5 mg/kg/day	LOAEL	Fertility
Fertility & Early Embryonic Development-Females	Rabbit	Oral	1 mg/kg/day	NOAEL	Fertility, Reproductive toxicity
Fertility & Early Embryonic Development-Females	Rat	Oral	1 mg/kg/day	LOAEL	Developmental toxicity
Embryo / Fetal Development	Rat	Oral	0.45 mg/kg/day	NOAEL	Maternal Toxicity
Embryo / Fetal Development	Rat	Oral	0.45 mg/kg/day	LOAEL	Fetotoxicity

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Temsirolimus

Bacterial Mutagenicity (Ames)	<i>Salmonella</i> , <i>E. coli</i>	Negative
Mammalian Cell Mutagenicity	Mouse Lymphoma	Negative
Chromosome Aberration	Chinese Hamster Ovary (CHO) cells	Negative
<i>In Vivo</i> Micronucleus	Mouse Bone Marrow	Negative

Carcinogen Status:

Carcinogenicity of the mixture has not been determined. Alcohol is listed as a carcinogen by IARC. The IARC monograph examining the carcinogenic potential of ethanol examined only alcoholic beverages.

Ethanol

IARC:	Group 1 (Carcinogenic to Humans)
OSHA:	Listed

12. ECOLOGICAL INFORMATION

Environmental Overview: The environmental characteristics of this mixture have not been fully evaluated. See aquatic toxicity data for individual components below: Releases to the environment should be avoided.

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

Temsirolimus

<i>Pseudokirchneriella subcapitata</i> (Green Alga)	OECD	EbC50	72 Hours	0.063 mg/L
<i>Pimephales promelas</i> (Fathead Minnow)	OECD	LC50	96 Hours	> 4.8 mg/L
<i>Daphnia Magna</i> (Water Flea)	OECD	EC50	48 Hours	> 3.6 mg/L

Ethanol

Fingerling Trout	NPDES	LC50	24 Hours	11,200 mg/L
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SAFETY DATA SHEET

Material Name: Torisel Injection
Revision date: 26-Nov-2013

Page 7 of 9
Version: 1.1

12. ECOLOGICAL INFORMATION

<i>Oncorhynchus mykiss</i> (Rainbow Trout)	NPDES	LC50	96 Hours	12,900 mg/L
<i>Pimephales promelas</i> (Fathead Minnow)	NPDES	LC50	96 Hours	14,200 mg/L

Bacterial Inhibition: (Inoculum, Method, End Point, Result)

Temsirolimus

Activated sludge OECD EC50 > 1 mg/L

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods:

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

The following refers to all modes of transportation unless specified below.

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

UN number:	UN 1170
UN proper shipping name:	Ethanol solution
Transport hazard class(es):	3
Packing group:	II
Flash Point (°C):	21.1

Flash Point (°C):	21.1
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15. REGULATORY INFORMATION

EU Indication of danger: Toxic to Reproduction: Category 2
Flammable

EU Risk Phrases:
R10 - Flammable.
R60 - May impair fertility.
R62 - Possible risk of impaired fertility.

OSHA Label:

DANGER
Flammable liquid and vapor.
May damage fertility or the unborn child

SAFETY DATA SHEET

Material Name: Torisel Injection
Revision date: 26-Nov-2013

Page 8 of 9
Version: 1.1

15. REGULATORY INFORMATION

Canada - WHMIS: Classifications

WHMIS hazard class:

Class D, Division 2, Subdivision A

Class B, Division 2



Citric acid, anhydrous

California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	201-069-1

DL-Alpha tocopherol

California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	233-466-0

Ethanol

California Proposition 65	carcinogen initial date 4/29/11 in alcoholic beverages developmental toxicity initial date 10/1/87 in alcoholic beverages
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	200-578-6

Propylene glycol

California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	200-338-0

Temsirolimus

California Proposition 65	Not Listed
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R11 - Highly flammable.

R60 - May impair fertility.

R61 - May cause harm to the unborn child.

R50/53 - Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Data Sources:

Pfizer proprietary drug development information. Publicly available toxicity information. Safety data sheets for individual ingredients.

SAFETY DATA SHEET

Material Name: Torisel Injection
Revision date: 26-Nov-2013

Page 9 of 9
Version: 1.1

Reasons for Revision: Updated Section 2 - Hazard Identification.

Prepared by: Product Stewardship Hazard Communication
Pfizer Global Environment, Health, and Safety Operations

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End of Safety Data Sheet