

Material Safety Data Sheet

ANSI Format

Diluent for Torisel

Preparation Date 28-Mar-2007 Revision Date 09-Mar-2009 Revision Number 2

1. PRODUCT AND COMPANY IDENTIFICATION

Product NameDiluent for ToriselCommon NameNot availableChemical NameNot applicable

Synonyms Torisel Diluent, Temsirolomus Diluent
Product Use Diluent for Pharmaceutical Product

Classification Not applicable

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

Flammable

Appearance LiquidPhysical StateLiquidOdor Slight Alcohol odor

Potential Physical Hazards Flammable liquid

Potential Health Effects

Eyes Irritating to eyes

SkinProlonged skin contact may defat the skin and produce dermatitisInhalationMay cause mucous membrane and upper respiratory tract irritation

Ingestion Not available

Other The most common effects may include drowsiness, flushing, nausea, difficulty breathing,

headache, dizziness, irritation, mental depression, excitation, symptoms of drunkeness,

impaired mental and/or physical abilities. May cause harm to the unborn child.

Therapeutic Target Organ(s) Central nervous system, liver

Ethanol listed by NTP and IARC

Potential Environmental Effects See Section 12

3. COMPOSITION/INFORMATION ON INGREDIENTS

Common Name	CAS-No	Composition
Polysorbate 80	9005-65-6	39%

Common Name	CAS-No	Composition
Ethanol	64-17-5	19.4%
Polyethylene Glycol 400	25322-68-3	Remainder

4. FIRST AID MEASURES

Eye Contact In case of contact with eyes, rinse immediately with plenty of water for 15 mintues and seek

medical advice

Skin Contact Wash off immediately with soap and plenty of water

Inhalation Artificial respiration and/or oxygen may be necessary

Ingestion Immediate medical attention is not required

5. FIRE-FIGHTING MEASURES

Flammable Properties Flammable liquid.

Extinguishing Media

Suitable Extinguishing Media Unsuitable Extinguishing

Media

Use alcohol-resistant foam, dry chemical, or Carbon dioxide 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): IC

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 Handle in accordance with good industrial hygiene and safety practice

Storage Keep container tightly closed

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Common Name Exposure Guideline

Ethanol 1900 mg/m³

Engineering Controls Apply technical measures to comply with the occupational exposure guideline

Personal Protective Equipment

Eye/face Protection Provide eye protection based on risk assessment. Skin Protection For prolonged or repeated exposure use protective gloves

Respiratory Protection Base respirator selection on a risk assessment.

General Hygiene Considerations

When using, do not eat, drink or smoke

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

9. PHYSICAL AND CHEMICAL PROPERTIES

Liquid **Physical State Appearance** Liquid

Yellowish Color Odor Slight Alcohol odor

Odor Threshold Not available

Not available pН

1.03 **Specific Gravity Water Solubility** Not available Not available Not available Solubility **Evaporation Rate** Not available Vapor Pressure Not available

Partition Coefficient (n-octanol/water)

Viscosity 43 cps

Boiling Point Not available **Autoignition Temperature** Not available Method None

Flash Point 24.44444°C

Not applicable **Melting Point**

Flammability Limits in Air

Upper Not available Lower Not available

Upper Not applicable 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

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

Ethanol

No Toxicologic EffectRepeated 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

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).

Ethanol

Target Organ(s) of Toxicity No data available

12. ECOLOGICAL INFORMATION

Chemical Fate Information

Ethanol

Mobility May adsorb on sludge or particles in natural waters.

BiodegradabilityNot availableStability in WaterHydrolyses in water.BioaccumulationBioaccumulative potential.

Ecotoxicity

Ethanol

Microorganisms EC50 > Aqueous solubility limit

DaphniaEC50/daphnia > > Aqueous solubility limit mg/l, NOEC = > Aqueous solubility limit mg/lFishLC50/96h/fathead minnow > Aqueous solubility limit, NOEC > 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)

Canadian Transport of Dangerous Goods (TDG)

International Civil Aviation Organization (ICAO)

Not regulated

Not regulated

International Air Transport Association (IATA)

Proper Shipping Name Consumer Commodity

Hazard Class 9 UN-No ID 8000

International Maritime Dangerous Goods (IMDG)/International Not regulated

Maritime Organization (IMO)

Transport of Dangerous Goods by Rail (RID)

Not regulated Not regulated

(ADN)

15. REGULATORY INFORMATION

USA

Federal Regulations

OSHA Regulatory Status

This material is 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

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 Determined

WHMIS Hazard Class

Non-controlled

European Union

Not Determined

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 Administrative

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