Material Safety Data Sheet
ANSI Format

Tygacil

Preparation Date 09-Jul-2007 **Revision Date** 08-Dec-2008 **Revision Number** 5

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name	Tygacil
Common Name	Tygacil (Tigecycline) for injection
Chemical Name	Not applicable
Synonyms	Tigecycline, Tigecycline for Injection, Reformulated Tygacil
Product Use	Pharmaceutical product
Classification	Anti-infective 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 is a research material that may affect body functions

Appearance Pharmaceutical powder **Physical State** Solid **Odor** Not available

Potential Physical Hazards Powders and solids are presumed to be combustible.

Potential Health Effects

Eyes	May cause mechanical eye irritation
Skin	Not available
Inhalation	Not available
Ingestion	Not available
Other	The most common effects may include anaphylaxis photosensitivity pseudotumor cerebri pancreatitis anti-anabolic action superinfection nausea vomiting diarrhea fever abdominal pain blood effects headache hypertension cough increase pain abnormal healing dizziness swelling abscess labored breathing constipation pruritus asthenia/weakness rash hypotension insomnia sweating phlebitis and back pain May cause harm to the unborn child. May cause harm to breastfed babies. Please see Patient Package Insert for further information.
Therapeutic Target Organ(s)	Systemic
	Not listed by OSHA, NTP or IARC.

Potential Environmental Effects See Section 12

3. COMPOSITION/INFORMATION ON INGREDIENTS

Common Name	CAS-No	Composition
Inactive Ingredients	Not applicable	Remainder
Tigecycline	220620-09-7	50 mg/vial
Lactose Monohydrate	64044-51-5	106 mg/vial
Hydrochloric Acid	7647-01-0	As needed to adjust pH
Sodium Hydroxide	1310-73-2	As needed to adjust pH

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 Presumed to be a combustible particulate solid.

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

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**
Tigecycline	70 mcg/m^3

Engineering Controls Apply technical measures to comply with the occupational exposure guideline Local exhaust ventilation is needed for open handling or where aerosols may be generated.

Personal Protective Equipment

Eye/face Protection	Provide eye protection based on risk assessment.
Skin Protection	Wear nitrile or latex gloves. Wear protective garment.
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 Consult a health and safety professional for specific PPE, respirator, and risk assessment guidance

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	Pharmaceutical powder	**Physical State**	Solid
Color	Orange	**Odor**	Not available
Odor Threshold	Not available		
pH	4.8		
Specific Gravity	Not applicable	**Water Solubility**	Not available
Solubility	Not applicable	**Evaporation Rate**	Not applicable
Partition Coefficient (n-octanol/water)	Not available	**Vapor Density**	Not applicable
Vapor Pressure	Not applicable		
Boiling Point	Not applicable	**Autoignition Temperature**	Not applicable
Flash Point	Not applicable	**Method**	None
Melting Point	Not available		
Flammability Limits in Air	**Upper** Not applicable	**Lower** Not applicable	
Explosion Limits	**Upper** Not applicable	**Lower** Not applicable	

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

The following effects are based on the Active Pharmaceutical Ingredient.

Acute Toxicity

Tigecycline

LD50 Oral	160 mg/kg rats IV 124 mg/kg male mice 98 mg/kg female mice
Acute Dermal Irritation	Not applicable
Primary Eye Irritation	Not applicable
Sensitization	Not applicable

Multiple Dose Toxicity

Tigecycline

No Toxicologic Effect Dose/Species/Study Length:	Effects on body weight, food consumption, blood, serum chemistry, bone discoloration (rats only), bone marrow, spleen, gastrointestinal tract (dogs only), and kidney were seen in subacute toxicity studies in rats and dogs.

Maximum Tolerated Dose (MTD), Oral

Tigecycline

Carcinogenicity	No studies to assess the carcinogenic potential have been performed.
Genetic Toxicity	No evidence of mutagenicity was observed in a battery of *in vitro* and *in vivo* assays.
Reproductive Toxicity	See Developmental Toxicity.
Developmental Toxicity	Animal studies indicate no teratogenicity in rats and rabbits. There was a slight reduction in fetal weights and an increased incidence of musculoskeletal anomalies.

Tigecycline

Target Organ(s) of Toxicity	No data available

12. ECOLOGICAL INFORMATION

The following effects are based on the Active Pharmaceutical Ingredient.

Chemical Fate Information

Tigecycline

Mobility	Not available
Biodegradability	Inherent biodegradability = 36 % after 46 days.
Stability in Water	Hydrolytically unstable at pH 2-11.
Bioaccumulation	Bioaccumulation is unlikely.

Ecotoxicity

Tigecycline

Microorganisms	EC50/3h/bacteria = 140 mg/l
Algae	Not available
Daphnia	EC50/48h/daphnia = 2.0 mg/l NOEC = 0.39 mg/l
Fish	Not available

13. DISPOSAL CONSIDERATIONS

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

14. TRANSPORT INFORMATION

Transport Information This material is not classified as hazardous for transport.

U.S. Department of Transport (DOT)	Not regulated
Canadian Transport of Dangerous Goods (TDG)	Not regulated
International Civil Aviation Organization (ICAO)	Not regulated
International Air Transport Association (IATA)	Not regulated
International Maritime Dangerous Goods (IMDG)/International Maritime Organization (IMO)	Not regulated
Transport of Dangerous Goods by Rail (RID)	Not regulated
Transport of Dangerous Goods by Road (ADR)	Not regulated
Transportation of Dangerous Goods via Inland Waterways (ADN)	Not regulated

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
This product does not contain any Proposition 65 chemicals

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.
Symbol(s) Xi - Irritant.
N - Dangerous for the environment
R -phrase(s)
R36 - Irritating to eyes R52 - Harmful to aquatic organisms R63 - Possible risk of harm to the unborn child R64 - May cause harm to breastfed babies
S -phrase(s)
S13 - Keep away from food, drink and animal feedingstuffs S25 - Avoid contact with eyes S36 - Wear suitable protective clothing S37 - Wear suitable gloves S38 - In case of insufficient ventilation, wear suitable respiratory equipment S61 - Avoid release to the environment. Refer to special instructions/safety data sheets

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	Change to OEG Changes to Section 2,15

Disclaimer:

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End of MSDS