

Preparation Date 09-Jul-2007

Revision Date 08-Dec-2008

Revision Number 5

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

Product Name Tygacil 150
Common Name Tygacil (Tigecycline) for injection
Chemical Name Not applicable
Synonyms Not available
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 Chemtec USA, Puerto Rico, Canada 1-800-424-9300
 Chemtec International 1-703-527-3887

2. COMPOSITION/INFORMATION ON INGREDIENTS

Common Name	CAS-No	EC No.	Composition	Classification
Inactive Ingredients	Not applicable	Not applicable	Remainder	Not applicable
Tigecycline	220620-09-7	None assigned	150 mg/vial	Xi, N, R36/52/61/64, S13/36/37/38/61
Lactose Monohydrate	64044-51-5	None Assigned	300 mg/vial	Not Applicable
Hydrochloric Acid	7647-01-0	231-595-7	As needed to adjust pH	C, R34/37, S26/36/45
Sodium Hydroxide	1310-73-2	215-185-5	As needed to adjust pH	C; R35; S26, 37/39, 45

3. HAZARDS IDENTIFICATION

Emergency Overview

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

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.
<u>Potential Environmental Effects</u>	See Section 12

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 immediately with soap and plenty of water
Inhalation	Artificial respiration and/or oxygen may be necessary
Ingestion	Immediate medical attention is required

5. FIRE-FIGHTING MEASURES

Flammable Properties	Not flammable
<u>Extinguishing Media</u>	
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.

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	No special safety precautions required

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Common Name Tigecycline	Exposure Guideline 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	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 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 <i>in vitro</i> and <i>in vivo</i> 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.
------------------------------	---

15. REGULATORY INFORMATION

In accordance with local and national regulations:

Contains	Tygacil
Symbol(s)	Xi - Irritant. N - Dangerous for the environment

R -phrase(s)

R36 - Irritating to eyes
R52 - Harmful to aquatic organisms
R61 - May cause 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 Directive 2001/58/EC.
List of References	See Patient Package Insert for more information.
Revision Summary	Change to OEG Changes to Section 2,15

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