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:
Chemtrec USA, Puerto Rico, Canada 1-800-424-9300
Chemtrec International 1-703-527-3887

2. COMPOSITION/INFORMATION ON INGREDIENTS

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

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 |

| Potential Environmental Effects | 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

**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.

---

### 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/m³

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

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

Tigecycline

<table>
<thead>
<tr>
<th>Microorganisms</th>
<th>EC50/3h/bacteria = 140 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Algae</td>
<td>Not available</td>
</tr>
<tr>
<td>Daphnia</td>
<td>EC50/48h/daphnia = 2.0 mg/l NOEC = 0.39 mg/l</td>
</tr>
<tr>
<td>Fish</td>
<td>Not available</td>
</tr>
</tbody>
</table>

Bioaccumulation

Bioaccumulation is unlikely.

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:
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End of MSDS