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

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-212-573-2222

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
International CHEMTREC (24 hours): +1-703-527-3887
Contact E-Mail: pfizer-MSDS@pfizer.com

Material Name: Tygacil

<table>
<thead>
<tr>
<th>Trade Name:</th>
<th>TYGACIL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Compound Number:</td>
<td>WAY-156936; GAR-936</td>
</tr>
<tr>
<td>Synonyms:</td>
<td>Tigecycline For Injection for intravenous use</td>
</tr>
<tr>
<td>Chemical Family:</td>
<td>Tetracycline derivative</td>
</tr>
<tr>
<td>Intended Use:</td>
<td>Pharmaceutical product used as Antibiotic agent</td>
</tr>
</tbody>
</table>

2. HAZARDS IDENTIFICATION

Appearance: Orange powder
Signal Word: DANGER

Statement of Hazard:
May damage the unborn child.
Causes severe eye damage.
May cause allergic skin reaction.
Very toxic to aquatic life with long lasting effects.

Additional Hazard Information:
Long Term:
Repeat-dose studies in animals have shown a potential to cause adverse effects on the developing fetus. High doses of tetracyclines can cause a liver condition known as fatty liver. Individuals who suffer from high cholesterol, high triglycerides, or have alcoholic liver disease may be more susceptible. May produce kidney toxicity if kidney damage already exists (based on animal data).

Known Clinical Effects:
May cause effects similar to those seen in clinical use including transient diarrhea, nausea and abdominal pain. Symptoms of chronic exposure to tetracyclines include redness and swelling of the skin, rash, chills, tooth discoloration, yellowing of the skin and eyes, nausea, vomiting, diarrhea, stomach pain, and chest pain. Individuals sensitive to this material or other materials in its chemical class may develop allergic reactions. Wheezing, asthma, low or high blood pressure, dizziness, lung congestion, blood changes (leukocytosis, atypical lymphocytes, toxic granulation of granulocytes and thrombocytopenia purpura), convulsion or shock may also occur. Clinical use of this drug has caused inflammation of the pancreas (pancreatitis), liver effects, increased mortality. Photosensitivity has been reported in some individuals taking tetracyclines.

EU Indication of danger: Irritant
Toxic to reproduction: Category 1
Dangerous for the Environment

EU Hazard Symbols:
2. HAZARDS IDENTIFICATION

EU Risk Phrases:
- R41 - Risk of serious damage to eyes.
- R61 - May cause harm to the unborn child.
- R43 - May cause sensitization by skin contact.
- R50/53 - Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

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

<table>
<thead>
<tr>
<th>Hazardous</th>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Tigecycline</td>
<td>220620-09-7</td>
<td>Not Listed</td>
<td>Repr.Cat.1; R61 , R41-43 ; R50/53</td>
<td>30-35</td>
</tr>
<tr>
<td></td>
<td>SODIUM HYDROXIDE</td>
<td>1310-73-2</td>
<td>215-185-5</td>
<td>C; R35</td>
<td>**</td>
</tr>
<tr>
<td></td>
<td>HYDROCHLORIC ACID</td>
<td>7647-01-0</td>
<td>231-595-7</td>
<td>T; R23 C; R35</td>
<td>**</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lactose NF, monohydrate</td>
<td>64044-51-5</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

Additional Information:
- ** to adjust pH
- 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.
5. FIRE FIGHTING MEASURES

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

Hazardous Combustion Products: Emits toxic fumes of carbon monoxide, carbon dioxide, and nitrogen oxides.

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

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

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 spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. 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: Minimize dust generation. Avoid breathing dust. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. 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.

<table>
<thead>
<tr>
<th>Material Name: Tygacil</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pfizer OEL TWA-8 Hr:</strong></td>
</tr>
</tbody>
</table>

SODIUM HYDROXIDE

| ACGIH Ceiling Threshold Limit: | 2 mg/m³ |
| Australia PEAK: | 2 mg/m³ |
| Austria OEL - MAKs: | 2 mg/m³ |
| Bulgaria OEL - TWA: | 2.0 mg/m³ |
| Czech Republic OEL - TWA: | 1 mg/m³ |
## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Country</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Estonia OEL - TWA</td>
<td>1 mg/m³</td>
</tr>
<tr>
<td>France OEL - TWA</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Greece OEL - TWA</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Hungary OEL - TWA</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Japan - OELs - Ceilings</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Latvia OEL - TWA</td>
<td>0.5 mg/m³</td>
</tr>
<tr>
<td>OSHA - Final PELS - TWAs</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Poland OEL - TWA</td>
<td>0.5 mg/m³</td>
</tr>
<tr>
<td>Slovakia OEL - TWA</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Slovenia OEL - TWA</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Sweden OEL - TWAs</td>
<td>1 mg/m³</td>
</tr>
</tbody>
</table>

### HYDROCHLORIC ACID

**ACGIH Ceiling Threshold Limit:** 2 ppm

<table>
<thead>
<tr>
<th>Country</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia PEAK</td>
<td>5 ppm</td>
</tr>
<tr>
<td>Austria OEL - MAKs</td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Belgium OEL - TWA</td>
<td>5 ppm</td>
</tr>
<tr>
<td>Bulgaria OEL - TWA</td>
<td>5 ppm</td>
</tr>
<tr>
<td>Czech Republic OEL - TWA</td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Estonia OEL - TWA</td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Germany - TRGS 900 - TWAs</td>
<td>2 ppm</td>
</tr>
<tr>
<td>Germany (DFG) - MAK</td>
<td>2 ppm</td>
</tr>
<tr>
<td>Greece OEL - TWA</td>
<td>5 ppm</td>
</tr>
<tr>
<td>Hungary OEL - TWA</td>
<td>5 ppm</td>
</tr>
<tr>
<td>Ireland OEL - TWAs</td>
<td>5 ppm</td>
</tr>
<tr>
<td>Italy OEL - TWA</td>
<td>5 ppm</td>
</tr>
<tr>
<td>Japan - OELs - Ceilings</td>
<td>5 ppm</td>
</tr>
<tr>
<td>Latvia OEL - TWA</td>
<td>5 ppm</td>
</tr>
<tr>
<td>Lithuania OEL - TWA</td>
<td>5 ppm</td>
</tr>
<tr>
<td>Luxembourg OEL - TWA</td>
<td>5 ppm</td>
</tr>
<tr>
<td>Malta OEL - TWA</td>
<td>5 ppm</td>
</tr>
<tr>
<td>Netherlands OEL - TWA</td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Poland OEL - TWA</td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Romania OEL - TWA</td>
<td>8 mg/m³</td>
</tr>
</tbody>
</table>
8. EXPOSURE CONTROLS / PERSONAL PROTECTION


Engineering Controls: Engineering controls should be used as the primary means to control exposures. Use process containment, local exhaust ventilation, or other engineering controls to maintain airborne levels within the OEB range.

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: Wear impervious gloves to prevent skin contact.

Eyes: Wear safety goggles as minimum protection.

Skin: Wear impervious protective clothing to prevent skin contact - consider use of disposable clothing where appropriate.

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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Material Name: Tygacil

Physical State: Powder
Molecular Formula: Mixture
Color: Orange
Molecular Weight: Mixture

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)

HYDROCHLORIC ACID
Rat Oral LD 50 238-277 mg/kg

Tigecycline
Mouse (M) IV LD50 124 mg/kg
Mouse (F) IV LD50 98 mg/kg
Rat IV LD50 106 mg/kg
11. TOXICOLOGICAL INFORMATION

Irritation / Sensitization: (Study Type, Species, Severity)

**Tigecycline**
- Antigenicity- Passive cutaneous anaphylaxis: Rat, Negative
- Antigenicity- Passive cutaneous anaphylaxis: Mouse, Negative
- Skin Corrosivity (*In vitro*, RHE): Negative
- Eye Irritation (*In vitro*, BCOP): Negative
- Eye Irritation: Rabbit, Severe
- Skin Sensitization - LLNA: Mouse, Positive

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

**Tigecycline**
- 13 Week(s), Dog: No route specified, 1.5 mg/kg/day, NOAEL, Lymphoid tissue
- 26 Week(s), Rat: Intravenous, 6 mg/kg/day, NOAEL, No effects at maximum dose
- 13 Week(s), Rat: No route specified, 2 mg/kg/day, NOAEL, Lymphoid tissue

Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

**Tigecycline**
- Embryo / Fetal Development, Rabbit: Intravenous, 4 mg/kg/day, NOAEL, No effects at maximum dose
- Embryo / Fetal Development, Rat: No route specified, 4 mg/kg/day, NOAEL, Maternal Toxicity, Fetotoxicity
- Embryo / Fetal Development, Rabbit: No route specified, 4 mg/kg/day, NOAEL, No effects at maximum dose
- Peri-/Postnatal Development, Rat: Intravenous, 12 mg/kg/day, NOAEL, No effects at maximum dose

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

**Tigecycline**
- *In Vitro* Chromosome Aberration: Chinese Hamster Ovary (CHO) cells, Negative
- *In Vivo* Micronucleus: Mouse, Negative
- *In Vitro* Forward Mutation Assay: Mouse Lymphoma, Negative

Carcinogen Status: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

HYDROCHLORIC ACID
- IARC: Group 3 (Not Classifiable)

12. ECOLOGICAL INFORMATION

Environmental Overview: Toxic to aquatic organisms. May cause long term adverse effects in the aquatic environment.

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

**Tigecycline**
- *Daphnia magna* (Water Flea): OECD, EC50, 48 Hours, 2 mg/L
- *Pimephales promelas* (Fathead Minnow): OECD, LC50, 72 Hours, 0.26 mg/L
- *Daphnia Magna* (Water Flea): OECD, NOEC, 21 Days, 2.1 mg/L
- Algal Growth Inhibition: OECD, EC50, 72 Hours, 1.65 mg/L
- *Pimephales promelas* (Fathead Minnow): OECD, NOEC, 32 Days, 22 μg/L
- Midge: OECD, NOEC, 28 Days, > 94 mg/L

Aquatic Toxicity Comments: A greater than (>) symbol indicates that acute ecotoxicity was not observed at the maximum solubility. Since the substance is insoluble in aqueous solutions above this concentration, an acute ecotoxicity value (i.e. LC/EC50) is not achievable.
12. ECOLOGICAL INFORMATION

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

Tigecycline
Activated sludge OECD EC50 140 mg/L (hydrolyzed tygecycline)
Activated sludge OECD EC50 58 mg/L (unhydrolyzed tygecycline)

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 3077
UN proper shipping name: Environmentally Hazardous Substance, Solid, n.o.s (Tigecycline)
Transport hazard class(es): 9
Packing group: III
Environmental Hazard(s): Marine Pollutant

DOT
Not regulated for transport in non-bulk (< 400 kg) packages unless shipped by air or water or when shipped in bulk packages.

15. REGULATORY INFORMATION

EU Symbol: T N
EU Indication of danger: Irritant
Toxic to reproduction: Category 1
Dangerous for the Environment

EU Risk Phrases:
R41 - Risk of serious damage to eyes.
R61 - May cause harm to the unborn child.
R43 - May cause sensitization by skin contact.
R50/53 - Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

EU Safety Phrases:
S22 - Do not breathe dust.
S53 - Avoid exposure - obtain special instructions before use.
S36/37 - Wear suitable protective clothing and gloves.
15. REGULATORY INFORMATION

OSHA Label:
DANGER
May damage the unborn child.
Causes severe eye damage.
May cause allergic skin reaction.
Very toxic to aquatic life with long lasting effects.

Canada - WHMIS: Classifications

| WHMIS hazard class: | Class D, Division 2, Subdivision A |

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

**Lactose NF, monohydrate**
- California Proposition 65: Not Listed
- Australia (AICS): Present

**SODIUM HYDROXIDE**
- CERCLA/SARA Hazardous Substances and their Reportable Quantities: 1000 lb (454 kg)
- California Proposition 65: Not Listed
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- Standard for the Uniform Scheduling for Drugs and Poisons: Schedule 5
- EU EINECS/ELINCS List: 215-185-5

**HYDROCHLORIC ACID**
- CERCLA/SARA 313 Emission reporting: 1.0 %
- CERCLA/SARA Hazardous Substances and their Reportable Quantities: 5000 lb (2270 kg)
- CERCLA/SARA - Section 302 Extremely Hazardous TPQs: 500 lb
- California Proposition 65: Not Listed
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- Standard for the Uniform Scheduling for Drugs and Poisons: Schedule 5
- EU EINECS/ELINCS List: 231-595-7
16. OTHER INFORMATION

Text of R phrases and GHS Classification abbreviations mentioned in Section 3

R41 - Risk of serious damage to eyes.
R43 - May cause sensitization by skin contact.
R61 - May cause harm to the unborn child.
R35 - Causes severe burns.
R23 - Toxic by inhalation.
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.

Reasons for Revision: Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 14 - Transport Information. Updated Section 15 - Regulatory Information. Updated Section 7 - Handling and Storage.


Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet