<table>
<thead>
<tr>
<th><strong>SECTION 1: Identification of the substance/mixture and of the company/undertaking</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1.1. Product identifier</strong></td>
</tr>
<tr>
<td><strong>Product name</strong></td>
</tr>
<tr>
<td><strong>Product code</strong></td>
</tr>
<tr>
<td><strong>Synonyms</strong></td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>1.2. Relevant identified uses of the substance or mixture and uses advised against</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Use</strong></td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>1.3. Details of the supplier of the safety data sheet</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Company information</strong></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>1.4. Emergency telephone number</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Emergency telephone number</strong></td>
</tr>
</tbody>
</table>

*1 referring to: Tocilizumab

<table>
<thead>
<tr>
<th><strong>SECTION 2: Hazards identification</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Classification of the substance or mixture / Label elements</strong></td>
</tr>
<tr>
<td><strong>GHS Classification</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Other hazards</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Note</strong></td>
</tr>
</tbody>
</table>
SECTION 3: Composition/information on ingredients

Characterization
- tocilizumab with other inactive ingredients
  1 vial contains 80 mg tocilizumab

Ingredients

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Concentration</th>
<th>GHS-Classification (pure ingredient)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tocilizumab</td>
<td>2%</td>
<td></td>
</tr>
<tr>
<td>375823-41-9</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

SECTION 4: First aid measures

4.1. Description of first aid measures

Eye contact
- rinse immediately with tap water for 10 minutes - open eyelids forcibly

Skin contact
- remove immediately contaminated clothes, wash affected skin with water and soap - do not use any solvents

Inhalation
- remove the casualty to fresh air
- in the event of symptoms get medical treatment

4.2. Most important symptoms and effects, both acute and delayed

Note
- no information available

4.3. Indication of any immediate medical attention and special treatment needed

Note to physician
- treat symptomatically

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media
- adapt extinguishing media to surrounding fire conditions

Flash point (liquid)
- not applicable

5.2. Special hazards arising from the substance or mixture

Specific hazards
- no particular hazards known

5.3. Advice for firefighters

Protection of fire-fighters
- precipitate gases/vapours/mists with water spray
## SECTION 6: Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

**Personal precautions** - no special precautions required

### 6.2. Environmental precautions

**Environmental protection** - no special environmental precautions required

### 6.3. Methods and material for containment and cleaning up

**Methods for cleaning up** - rinse with plenty of water

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

**Suitable materials** - glass

### 7.2. Conditions for safe storage, including any incompatibilities

**Storage conditions**
- 2 - 8 °C
- do not freeze
- protected from light

**Validity**
- see "best use before" date stated on the label, after opening the content should be used within a short period

**Packaging materials**
- vials
- keep it in the outer carton in order to protect from light

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

**Threshold value (Roche) air**
- IOEL (Internal Occupational Exposure Limit): 0.4 mg/m³

### 8.2. Exposure controls

**Respiratory protection**
- Respiratory protection is recommended as a precaution to minimize exposure. Effective engineering controls are considered to be the primary means to control worker exposure. Respiratory protection should not substitute for feasible engineering controls.
- respiratory protection not necessary during normal operations

**Hand protection**
- protective gloves (eg made of neoprene, nitrile or butyl rubber)
### SECTION 9: Physical and chemical properties

#### 9.1. Information on basic physical and chemical properties

**Color**
- colorless to slightly yellow
- clear to opalescent

**Form**
- clear solution
- sterile liquid

#### 9.2. Other information

Note: no information available

### SECTION 10: Stability and reactivity

#### 10.1. Reactivity

Note: no information available

#### 10.2. Chemical stability

**Stability**
- does not contain any antimicrobial preservative; therefore, care must be taken to ensure the sterility of the prepared solution
- as for all other proteins, monoclonal antibodies are temperature-sensitive; the thermal denaturation has an impact on quality but does not affect Plant and Process Safety; during decomposition no flammable gas, no organic peroxide and no oxidising substances are created

#### 10.3. Possibility of hazardous reactions

Note: no information available

#### 10.4. Conditions to avoid

**Conditions to avoid**
- warming
- light
- heavy mechanical loads (shock, impact)

#### 10.5. Incompatible materials

Note: no information available
10.6. Hazardous decomposition products

Note - no information available

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity
- NOEL ≥ 150 mg/kg (i.v., rat) *1
- not bioavailable by oral administration *1

Subacute toxicity
- NOAEL 10 mg/kg/d (i.v., rat, 28 d) *1

Sensitization
- anaphylactic reactions may occur following the intravenous application of proteins; after inhalative exposure no cases of hypersensitivity have been described

Chronic toxicity
- NOAEL > 100 mg/kg/w (i.v., monkey; 6 months) *1

Mutagenicity
- not mutagenic (various in vitro test systems) *1

Note
- immunosuppressive agent *1
- therapeutic dose: 4 to 8 mg/kg/month *1
- elimination half-life: 6 to 9 d *1
- side effect(s) during therapy: liver damages, infectious episodes *1

Potential Health Effects
- Exposure: Inhalation, Ingestion, Skin contact, Eye contact
- Carcinogenicity: formulation not listed by NTP, IARC or OSHA

Additional Health Information
- Conditions Aggravated: Hypersensitivity to this material and other materials in its chemical class.

*1 referring to: Tocilizumab

SECTION 12: Ecological information

12.1. Toxicity

Ecotoxicity
- barely toxic for planktonic crustaceans (nominal concentration = 100 mg/l) (Daphnia magna)
  EC50 (48 h) > 100 mg active substance/l
  NOEC (48 h) 100 mg active substance/l
  (OECD No. 202) *2
- barely toxic for fish (nominal concentration = 100 mg/l) (zebrafish)
  LC50 (96 h) > 100 mg active substance/l
  NOEC (96 h) 100 mg active substance/l
  (OECD No. 203) *2
- no adverse influence on substrate biodegradation (activated sludge)
  concentration (14 d) 100 mg active substance/l
  (Manometric Respirometry Test, OECD No. 301 F) *2
ACTEMRA(R) Sterile Concentrate for Injection (80 mg)

- barely toxic for algae (nominal concentration = 100 mg/l)  
  (Scenedesmus (=Desmodesmus) subspicatus)  
  EC\textsubscript{50} (72 h) > 100 mg active substance/l  
  NOEC (72 h) 100 mg active substance/l  
  (OECD No. 201)  

12.2. Persistence and degradability

| Ready biodegradability | - readily biodegradable  
|                       | 89 % BOD/ThOD, 28 d  
|                       | ≥76 % active substance, 28 d  
|                       | (Manometric Respirometry Test, OECD No. 301 F) |

12.3. Bioaccumulative potential

- no information available

12.4. Mobility in soil

- no information available

12.5. Results of PBT and vPvB assessment

- no information available

12.6. Other adverse effects

- no information available

*2 referring to: ACTEMRA™ Sterile Concentrate for Injection (80, 200 & 400 mg)

SECTION 13: Disposal considerations

13.1. Waste treatment methods

- observe local/national regulations regarding waste disposal  
- drain very small quantities into wastewater treatment plant

SECTION 14: Transport information

- not classified by transport regulations, proper shipping name non-regulated

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

- FDA Exemption - not on inventory
**ACTEMRA(R) Sterile Concentrate for Injection (80 mg)**

### Reporting Requirements
- The United States Environmental Protection Agency (USEPA) has not established a Reportable Quantity (RQ) for releases of this material.
- In New Jersey, report all releases which are likely to endanger the public health, harm the environment or cause a complaint to the NJDEPE Hotline (1-609-292-5560) and to local officials.
- State and local regulations vary and may impose additional reporting requirements.

### SECTION 16: Other information

**Note**
- Please note this Safety Data Sheet for the bulk product does not apply for the finished, packaged medicinal product intended for the final user.

**Edition documentation**
- Changes from previous version in sections 2, 3, 16

The information in this safety data sheet is based on current scientific knowledge. It should not be taken as expressing or implying any warranty concerning product characteristics.