SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product name          ACTEMRA(R) SC Prefilled Syringes (162 mg/0.9 ml)
Product code          SAP-10141792
Synonyms              - Actemra SC
                      - ACTEMRA(R) SC Prefilled Syringes (180 mg/ml)

1.2. Relevant identified uses of the substance or mixture and uses advised against

Use                    ACTEMRA is a prescription medicine called an Interleukin-6 (IL-6) receptor antagonist. ACTEMRA SC is used to treat adults with moderately to severely active rheumatoid arthritis (RA).

1.3. Details of the supplier of the safety data sheet

Company information: Genentech, Inc.
1 DNA Way
South San Francisco
USA-CA 94080
United States of America

Phone                  001-(650) 225-1000
E-Mail                 info.sds@roche.com
US Chemtrec phone:     (800)-424-9300

1.4. Emergency telephone number

Emergency telephone number US Chemtrec phone: (800)-424-9300

SECTION 2: Hazards identification

Classification of the substance or mixture / Label elements

GHS Classification     no classification and labelling according to GHS

Other hazards

Note                 - no information available

SECTION 3: Composition/information on ingredients
**ACTEMRA(R) SC Prefilled Syringes (162 mg/0.9 ml)**

### Ingredients

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Concentration</th>
<th>GHS-Classification (pure ingredient)</th>
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<tbody>
<tr>
<td>Tocilizumab</td>
<td>~ 18 %</td>
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<tr>
<td>375823-41-9</td>
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### SECTION 4: First aid measures

#### 4.1. Description of first aid measures

- **Eye contact**: rinse with tap water for 20 minutes - open eyelids forcibly
- **Skin contact**: drench affected skin with water
- **Inhalation**: 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 - mop or flush the contaminated area with water

SECTION 7: Handling and storage

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions - 2 - 8 °C

Validity - 2 years, see "best use before" date stated on the label, in the unopened original container

Packaging materials - prefilled syringes

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Threshold value (Roche) air - IOEL (Internal Occupational Exposure Limit): 0.4 mg/m³ *1

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)

Eye protection - safety glasses

*1 referring to: Tocilizumab

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Color colorless to slightly yellow

Form sterile liquid

pH value 5.5 to 6.5

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

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 $\geq$ 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) $^1$

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

Local effects - no information available

Sensitization - no information available

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

Carcinogenicity - no information available

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Reproductive toxicity - no information available
STOT-single exposure - no information available
STOT-repeated exposure - no information available
Aspiration hazard - no information available
Note - immunosuppressive agent
- therapeutic dose: 4 to 8 mg/kg/month
- elimination half-life: 6 to 9 d
- side effect(s) during therapy: liver damages, infectious episodes

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 algae (nominal concentration = 100 mg/l)
(Scenedesmus (=Desmodesmus) subspicatus)
EC₅₀ (72 h) > 100 mg active substance/l
NOEC (72 h) 100 mg active substance/l
(OECD No. 201) *2
- 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

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) *2
12.3. Bioaccumulative potential

Note - no information available

12.4. Mobility in soil

Note - no information available

12.5. Results of PBT and vPvB assessment

Note - no information available

12.6. Other adverse effects

Note - no information available

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

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste from residues - observe local/national regulations regarding waste disposal

SECTION 14: Transport information

Note - not classified as Dangerous Good according to the Dangerous Goods Regulations, proper shipping name non-regulated

SECTION 15: Regulatory information

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

TSCA Status - FDA Exemption - not on inventory

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.
<table>
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<th>Note</th>
<th>Please note this Safety Data Sheet for the bulk product does not apply for the finished, packaged medicinal product intended for the final user.</th>
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<tr>
<td>Edition documentation</td>
<td>changes from previous version in sections 1</td>
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