Safety Data Sheet

ACTEMRA(R) SC Prefilled Syringes (162 mg/0.9 ml)

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

Enquiries:
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

Local representation:

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

Ingredients	Concentration	GHS-Classification (pure ingredient)
Tocilizumab 375823-41-9	~ 18 %	

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 ≥ 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	

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	*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 algae (nominal concentration = 100 mg/l) (Scenedesmus (=Desmodesmus) subspicatus) EC_{50} (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) EC_{50} (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) LC_{50} (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.

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 1

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.