Genentech
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Material Safety Data Sheet

ACTEMRA™ Sterile Concentrate for Injection (80, 200 & 400 mg)

1. Product and Company Identification

Product name	ACTEMRA™ Sterile Concentrate for Injection (80, 200 & 400 mg)
Product code	CSE-2024
Company information	Enquiries: Local representation: Hoffmann-La Roche Inc. 340 Kingsland Street USA-Nutley, N.J. 07110-1199 United States of America Phone 001-973/235 50 00 US Emergency phone: (800)-827-6243 US Chemtrec phone: (800)-424-9300

2. Composition/Information on ingredients

Ingredients	Concentration
Tocilizumab CAS: 375823-41-9	2 %

3. Hazards identification

Emergency Overview

Form	liquid
Color	colorless, clear
Hazard Overview	- May cause allergic reactions.
Potential Health Effects	- Exposure: Inhalation, Ingestion, Skin contact, Eye contact - Acute Effects: May cause allergic reactions., This material has not been tested as a whole; therefore, the information described below is based on one or more of its ingredients., This material is not likely to be significantly absorbed via occupational routes of entry due to its chemical structure and large molecular weight. - Chronic Effects: No adverse effects known - Carcinogenicity: not listed by NTP, IARC or OSHA
Additional Health Information	- Conditions Aggravated: Hypersensitivity to this material and other materials in its chemical class.

4. First-aid measures

Eye contact	- in case of contact with eyes rinse thoroughly with plenty of water and get medical advice
Skin contact	- remove immediately contaminated clothes, wash affected skin with plenty of water
Inhalation	- in case of inhalation remove to fresh air and seek medical aid
Ingestion	- consult physician

5. Fire-fighting measures

Suitable extinguishing media	- water spray jet, dry powder, foam, carbon dioxide
Flash point (liquid)	not applicable
Protection of fire-fighters	- use self-contained breathing apparatus
Special method of fire-fighting	- cool endangered containers with water spray

6. Accidental release measures

Personal precautions	- ensure adequate ventilation
Methods for cleaning up	- absorb small spills with absorbent material - Dike large spills and pump into metal drums or absorb with absorbent material. - Put saturated absorbent material into a suitable labeled open head drum. - Secure the drum cover and move the container to a safe holding area - Wash spill area thoroughly with soapy water

7. Handling and storage

Handling

Technical measures	- Use with adequate ventilation

Storage

Storage conditions	- 2 - 8 °C - protected from light

8. Exposure controls/Personal protection

Engineering Measures	- see 7.	
Monitoring		
Threshold value (Roche) air	- Category 1 (Roche Group Directive K1, Annex 3): IOEL > 100 µg/m3	*1
Note	- Exposure limits: There are no exposure limits specified for this material.	
Personal protective equipment		
Respiratory protection	- Respiratory protection is recommended as a precaution to minimze 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 - in case of intense formation of aerosols: particle mask	
Hand protection	- protective gloves	
Eye protection	- safety glasses	
Body protection	- protective clothing	
General protective and hygiene measures	- shower after work recommended	

*1 referring to: Tocilizumab

9. Physical and chemical properties

Color	colorless, clear
Form	liquid

10. Stability and reactivity

Stability	- stable under normal conditions
Conditions to avoid	- heat - light - Do not shake or freeze.

11. Toxicological information

Acute toxicity	- NOEL ≥ 150 mg/kg (i.v., rat)	*1
	- NOEL ≥ 100 mg/kg (i.v., monkey)	*1
	- not bioavailable by oral administration	*1
Subacute toxicity	- NOAEL 10 mg/kg/d (i.v., rat, 28 d)	*1

Local effects	-	not phototoxic (in vitro)	*1
Sensitization	-	anaphylactic reactions may occur following the intravenous application of proteins; rare cases of hypersensitivity have been described	*1
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

*1 referring to: Tocilizumab

12. Ecological information

Ready biodegradability	-	readily biodegradable 89 % BOD/ThOD, 28 d ≥ 76 % active substance, 28 d (Manometric Respirometry Test, OECD No. 301 F)
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)
	-	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)
	-	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)
	-	no adverse influence on substrate biodegradation (activated sludge) concentration (14 d) 100 mg active substance/l (Manometric Respirometry Test, OECD No. 301 F)

13. Disposal considerations

Waste from residues	-	incinerate in qualified installation with flue gas scrubbing
	-	observe local/national regulations regarding waste disposal
Contaminated packaging	-	Empty containers must be triple rinsed prior to disposal, recycling or reuse.
RCRA waste	-	not regulated under RCRA

14. Transport information

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

15. Regulatory information

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.

16. Other information

Use	- Therapeutic category: Immunosuppressive agent indicated for the treatment of rheumatoid arthritis.
Edition documentation	- changes from previous version in sections 8, 12

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.