SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard

Genentech
A Member of the Roche Group

ACTEMRA Vials 80 mg/4ml

Version	Revision Date:	Date of last issue: 06/13/2025
1.1	09/02/2026	Date of first issue: 06/13/2025

SECTION 1. IDENTIFICATION

Product name	:	ACTEMRA Vials 80 mg/4ml
Product code	:	RO487-7533/F04-01
Common name(s), synonym(s) of the substance	:	RoActemra

Manufacturer or supplier's details

Company name of supplier	:	Genentech, Inc.
Address	:	1 DNA Way South San Francisco, CA 94080 USA
Telephone	:	001-(650) 225-1000
E-mail address	:	info.sds@roche.com
Emergency telephone		
In case of emergencies:	:	US CHEMTREC PHONE (800)-424-9300

Recommended use of the chemical and restrictions on use

Recommended use	:	Formulated pharmaceutical active substance

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Hazards for the product as supplied

Not a hazardous substance or mixture.

Other hazards

None known.

GHS label elements

No hazard pictogram, no signal word, no hazard statement(s), no precautionary statement(s) required.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS No./Unique ID	Concentration (% w/w)	Trade secret
Tocilizumab	375823-41-9*	2	-
Sorbitan, mono-(9Z)-9-octadecenoate, poly(oxy-1,2-ethanediyl) derivs.	9005-65-6*	0.05	-
.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl	57-50-1*	5	-
di Sodium monohydrogen phosphate, dodecahydrate	10039-32-4*	0.15	-
Sodium dihydrogen phosphate dihydrate	13472-35-0*	0.17	-
Water	7732-18-5*	92	-

* Indicates that the identifier is a CAS No.

SECTION 4. FIRST AID MEASURES

General advice : Do not leave the victim unattended.

If inhaled : If unconscious, place in recovery position and seek medical advice.

If symptoms persist, call a physician.

In case of skin contact : Wash off with soap and water.

In case of eye contact : Remove contact lenses.

Protect unharmed eye.

If eye irritation persists, consult a specialist.

If swallowed : Keep respiratory tract clear.

Do not give milk or alcoholic beverages.

Never give anything by mouth to an unconscious person.

If symptoms persist, call a physician.

Most important symptoms and effects, both acute and delayed : None known.

Protection of first-aiders : First Aid responders should pay attention to self-protection and use the recommended protective clothing

Notes to physician : Treat symptomatically.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Unsuitable extinguishing media : High volume water jet

Specific hazards during fire fighting : No information available.

Hazardous combustion products : Carbon monoxide

Nitrogen oxides (NOx)

Sulfur oxides

Further information	:	Standard procedure for chemical fires. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Special protective equipment for fire-fighters	:	Wear self-contained breathing apparatus for firefighting if necessary.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	:	Refer to protective measures listed in sections 7 and 8.
Environmental precautions	:	If the product contaminates rivers and lakes or drains inform respective authorities.
Methods and materials for containment and cleaning up	:	Wipe up with absorbent material (e.g. cloth, fleece). Keep in suitable, closed containers for disposal.

SECTION 7. HANDLING AND STORAGE

Advice on protection against fire and explosion	:	Normal measures for preventive fire protection.
Advice on safe handling	:	For personal protection see section 8. Smoking, eating and drinking should be prohibited in the application area.
Conditions for safe storage	:	Electrical installations / working materials must comply with the technological safety standards.
Materials to avoid	:	No materials to be especially mentioned.

Storage temperature : Protect from heat and light

Further information on storage stability : No decomposition if stored and applied as directed.

Packaging material : Suitable material: Stainless steel, glass, Vials

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl	57-50-1	TWA	10 mg/m3	ACGIH
		TWA (Respirable)	5 mg/m3	NIOSH REL
		TWA (total)	10 mg/m3	NIOSH REL
		TWA (total dust)	15 mg/m3	OSHA Z-1
		TWA (respirable fraction)	5 mg/m3	OSHA Z-1
		TWA (Total dust)	15 mg/m3	OSHA P0
		TWA (respirable dust fraction)	5 mg/m3	OSHA P0
Tocilizumab	375823-41-9	IOEL	0.4 mg/m3	Roche Industrial Hygiene Committee (RIHC)

Personal protective equipment

Respiratory protection : General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided

by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

Hand protection

In case of contact through splashing:

Material	:	Nitrile rubber
Break through time	:	> 30 min
Glove thickness	:	> 0.11 mm

In case of full contact:

Material	:	butyl-rubber
Break through time	:	> 480 min
Glove thickness	:	> 0.4 mm

Remarks	:	Wear appropriate protective gloves to prevent skin contact. Replace torn or punctured gloves promptly.
Eye protection	:	Safety glasses
Skin and body protection	:	Protective suit
Hygiene measures	:	General industrial hygiene practice.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	Aqueous solution, Clear liquid, sterile
Color	:	light yellow

Odor	:	No data available
Odor Threshold	:	No data available
pH	:	No data available
Melting point/ range	:	No data available
Boiling point/boiling range	:	No data available
Flash point	:	No data available
Evaporation rate	:	No data available
Self-ignition	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapor pressure	:	No data available
Relative vapor density	:	No data available
Relative density	:	No data available

Density	:	No data available
Solubility(ies)		
Water solubility	:	completely miscible
Solubility in other solvents	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Autoignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, dynamic	:	No data available
Viscosity, kinematic	:	No data available
Explosive properties	:	No data available
Oxidizing properties	:	No data available
Particle characteristics		
Particle Size Distribution	:	Not applicable

SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	No dangerous reaction known under conditions of normal use.
Chemical stability	:	Proteins 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

Stable under normal conditions.

Possibility of hazardous reactions	:	Stable under recommended storage conditions. No hazards to be specially mentioned.
Conditions to avoid	:	No data available
Incompatible materials	:	Not applicable
Hazardous decomposition products	:	No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity
Not classified due to lack of data.

Components:

.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl:
Acute oral toxicity : LD50 Oral (Rat): 29,700 mg/kg

Tocilizumab:
Acute oral toxicity : Remarks: Not bioavailable by oral administration

Acute toxicity (other routes of administration) : No-observed-effect level (Rat): >= 150 mg/kg
Application Route: i.v.

Skin corrosion/irritation
Not classified due to lack of data.

Serious eye damage/eye irritation
Not classified due to lack of data.

Respiratory or skin sensitization

Skin sensitization
Not classified due to lack of data.

Respiratory sensitization
Not classified due to lack of data.

Germ cell mutagenicity
Not classified due to lack of data.

Components:

.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl:

Genotoxicity in vitro	:	Test Type: In vitro mammalian cell gene mutation test Result: negative

Tocilizumab:

Genotoxicity in vitro	:	Result: negative Remarks: In vitro tests did not show mutagenic effects

Carcinogenicity
Not classified due to lack of data.

Components:

.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl:

Remarks	:	No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

IARC No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

NTP No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity
Not classified due to lack of data.

STOT-single exposure
Not classified due to lack of data.

Components:

.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl:

Assessment	:	The substance or mixture is not classified as specific target organ toxicant, single exposure.

STOT-repeated exposure
Not classified due to lack of data.

Components:

.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl:

Assessment	:	The substance or mixture is not classified as specific target organ toxicant, repeated exposure.

Repeated dose toxicity

Components:

Tocilizumab:

Species	:	Rat
NOAEL	:	10 mg/kg bw/day
Application Route	:	i.v.
Exposure time	:	28 d
Remarks	:	Subacute toxicity

Aspiration toxicity
Not classified due to lack of data.

Components:

.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl:
No data available

Further information

Product:

Remarks	:	No data available

Components:

.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl:

Remarks	:	Health injuries are not known or expected under normal use.

Tocilizumab:

Remarks : anaphylactic reactions may occur following the intravenous application of proteins; rare cases of hypersensitivity have been described with other monoclonal antibodies

Endocrine disrupting properties

Components:

Tocilizumab:

Assessment : Does not have endocrine disrupting properties.

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl:

Ecotoxicology Assessment

Acute aquatic toxicity : This product has no known ecotoxicological effects.

Chronic aquatic toxicity : This product has no known ecotoxicological effects.

Toxicity Data on Soil : Not expected to adsorb on soil.

Other organisms relevant to the environment : No data available

Tocilizumab:

Toxicity to fish : LC50 (Brachydanio rerio (zebrafish)): > 100 mg/l

Exposure time: 96 h

Method: OECD Test Guideline 203

GLP: yes

Remarks: nominal concentration

NOEC (Brachydanio rerio (zebrafish)): 100 mg/l

Exposure time: 96 h

Method: OECD Test Guideline 203

GLP: yes

Remarks: nominal concentration

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 100 mg/l

Exposure time: 48 h

Test Type: Immobilization

Method: OECD Test Guideline 202

GLP: yes

Remarks: nominal concentration

NOEC (Daphnia magna (Water flea)): 100 mg/l

Exposure time: 48 h

Test Type: Immobilization

Method: OECD Test Guideline 202

GLP: yes

Remarks: nominal concentration

Toxicity to algae/aquatic plants : EC50 (Desmodesmus subspicatus (green algae)): > 100 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

GLP: yes

Remarks: nominal concentration

NOEC (Desmodesmus subspicatus (green algae)): 100 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

GLP: yes

Remarks: nominal concentration

Toxicity to microorganisms : (activated sludge): 100 mg/l

Exposure time: 14 d

Method: OECD Test Guideline 301F

GLP: yes

Remarks: no adverse influence on substrate biodegradation

Persistence and degradability

Components:

Tocilizumab:

Biodegradability : aerobic

Theoretical oxygen demand

Result: Readily biodegradable.

Biodegradation: >= 76 %

Exposure time: 28 d

Method: OECD Test Guideline 301F

GLP: yes

Bioaccumulative potential

Components:

.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl:

Partition coefficient: n-octanol/water : log Pow: -3.7 (68 °F / 20 °C)

Tocilizumab:

Partition coefficient: n-octanol/water : Remarks: No data available

Mobility in soil

No data available

Other adverse effects

Product:

Ozone-Depletion Potential : Regulation: 40 CFR Protection of Environment; Part 82 Protection of Stratospheric Ozone - CAA Section 602 Class I Substances

Remarks: This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A +

B).

Additional ecological information : No data available

Components:

Tocilizumab:

Results of PBT and vPvB assessment : Not persistent, bioaccumulative, and toxic (PBT).

Additional ecological information : No data available

Endocrine disrupting properties

Components:

Tocilizumab:

Assessment : Does not have endocrine disrupting properties.

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Can be disposed as waste water, when in compliance with local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG

Not regulated as a dangerous good

IATA-DGR

Not regulated as a dangerous good

IMDG-Code

Not regulated as a dangerous good

Transport in bulk according to IMO instruments
Not applicable

Domestic regulation

49 CFR

Not regulated as a dangerous good

Special precautions for user

Remarks : Not dangerous goods in the meaning of ADR/RID, ADN, IMDG-Code, ICAO/IATA-DGR

SECTION 15. REGULATORY INFORMATION

CERCLA Reportable Quantity
Listed substances in the product are at low enough levels to not be expected to exceed the RQ

SARA 304 Extremely Hazardous Substances Reportable Quantity
This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity
This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards : No SARA Hazards

SARA 313 : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

Clean Air Act
This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 112 (40 CFR 61).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCMI Intermediate or Final VOC's (40 CFR 60.489).

Clean Water Act
The following Hazardous Substances are listed under the U.S. CleanWater Act, Section 311, Table 116.4A:

di Sodium monohydrogen phosphate, dodecahydrate	10039-32-4	>= 0.1 - < 1 %

The following Hazardous Chemicals are listed under the U.S. CleanWater Act, Section 311, Table 117.3:

di Sodium monohydrogen phosphate, dodecahydrate	10039-32-4	>= 0.1 - < 1 %

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

This product does not contain any priority pollutants related to the U.S. Clean Water Act

US State Regulations

Massachusetts Right To Know

.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl	57-50-1

Pennsylvania Right To Know

Water	7732-18-5
.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl	57-50-1
di Sodium monohydrogen phosphate, dodecahydrate	10039-32-4

Maine Chemicals of High Concern

Product does not contain any listed chemicals

Vermont Chemicals of High Concern

Product does not contain any listed chemicals

Washington Chemicals of High Concern

Product does not contain any listed chemicals

California Permissible Exposure Limits for Chemical Contaminants

.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl	57-50-1

The ingredients of this product are reported in the following inventories:

AU AIIC	:	Not in compliance with the inventory
CA. DSL	:	This product contains the following components that are not on the Canadian DSL nor NDSL.
		Tocilizumab

NZ NZIoC	:	On the inventory, or in compliance with the inventory
JP ENCS	:	Not in compliance with the inventory
JP ISHL	:	Not in compliance with the inventory
KR KECI	:	Not in compliance with the inventory
PH PICCS	:	Not in compliance with the inventory
CN IECSC	:	Not in compliance with the inventory
TW TCSI	:	Not in compliance with the inventory
US TSCA	:	Product contains substance(s) not listed on TSCA inventory.
TH TECI	:	Not in compliance with the inventory

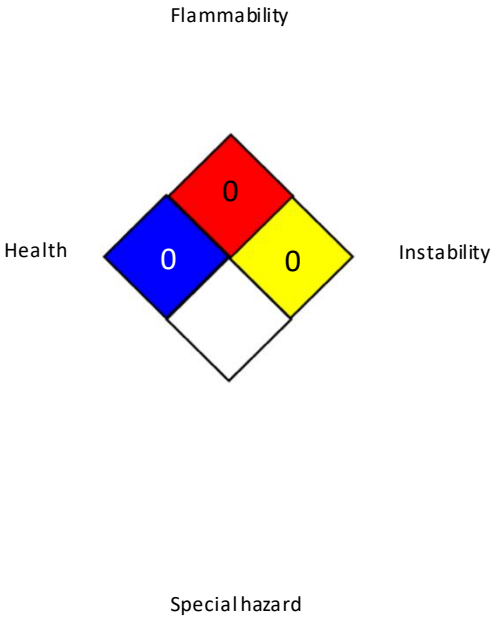
TSCA list
No substances are subject to a Significant New Use Rule.

No substances are subject to TSCA 12(b) export notification requirements.

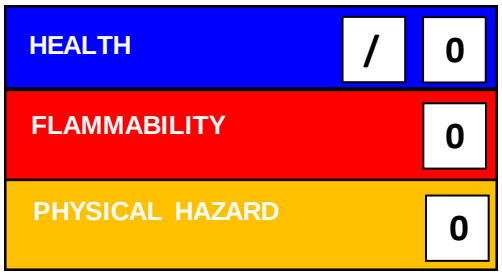
SECTION 16. OTHER INFORMATION

Further information

NFPA 704:



HMIS® IV / CED:



HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
NIOSH REL	:	USA. NIOSH Recommended Exposure Limits
OSHA P0	:	USA. Table Z-1-A Limits for Air Contaminants (1989 vacated values)
OSHA Z-1	:	USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
ACGIH / TWA	:	8-hour, time-weighted average
NIOSH REL / TWA	:	Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
OSHA P0 / TWA	:	8-hour time weighted average
OSHA Z-1 / TWA	:	8-hour time weighted average

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardization; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS -

Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organization for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorization and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Revision Date : 09/02/2026

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

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