

ACTEMRA(R) Vials 200 mg/10 ml

Version Revision Date: Date of last issue: 01-29-2020 1.4 09-05-2022 Date of first issue: 12-04-2015

SECTION 1. IDENTIFICATION

Product name : ACTEMRA(R) Vials 200 mg/10 ml

Product code : RO487-7533/F01

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

(800)-424-9300

USA

Telephone : 001-(650) 225-1000 E-mail address : info.sds@roche.com

Emergency telephone

Emergency telephone num- : US Chemtrec phone

ber

Recommended use of the chemical and restrictions on use

Recommended use : Formulated pharmaceutical active substance

Restrictions on use : For professional users only.

SECTION 2. HAZARDS IDENTIFICATION

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

Not a hazardous substance or mixture.

GHS label elements

Not a hazardous substance or mixture.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Tocilizumab	375823-41-9	2.0
Sorbitan, mono-(9Z)-9-octadecenoate, poly(oxy-1,2-	9005-65-6	0.05
ethanediyl) derivs.		
.alphaD-Glucopyranoside, .betaD-fructofuranosyl	57-50-1	5.0
di Sodium monohydrogen phosphate,	10039-32-4	0.15



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dodecahydrate		
Sodium dihydrogen phosphate di-	13472-35-0	0.17
hydrate		
Water	7732-18-5	> 92.0

SECTION 4. FIRST AID MEASURES

General advice : Do not leave the victim unattended.

If inhaled : Move to fresh air.

If unconscious, place in recovery position and seek medical

advice

If symptoms persist, call a physician.

In case of skin contact : If on skin, rinse well with water.

In case of eye contact : Immediately flush eye(s) with plenty of water.

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.

Rinse mouth with water.

Most important symptoms and effects, both acute and

delayed

None known.

Notes to physician : The first aid procedure should be established in consultation

with the doctor responsible for industrial medicine.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media : Use extinguishing measures that are appropriate to local cir-

cumstances and the surrounding environment.

Specific hazards during fire

fighting

No information available.

Hazardous combustion prod-

ucts

In case of fire hazardous decomposition products may be

produced such as: Carbon monoxide Nitrogen oxides (NOx)

Sulfur oxides

Further information : Standard procedure for chemical fires.

Use extinguishing measures that are appropriate to local cir-

cumstances and the surrounding environment.

Special protective equipment :

for fire-fighters

Wear self-contained breathing apparatus for firefighting if

necessary.



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SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protec- :

tive equipment and emer-

gency procedures

Refer to protective measures listed in sections 7 and 8.

Environmental precautions : Local authorities should be advised if significant spillages

cannot be contained.

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 ap-

plication area.

Conditions for safe storage : Electrical installations / working materials must comply with

the technological safety standards.

Further information on stor-

age conditions

See label, package insert or internal guidelines

Materials to avoid : No materials to be especially mentioned.

Storage temperature : Protected from heat and light

Further information on stor-

age stability

No decomposition if stored and applied as directed.

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
.alphaD- Glucopyranoside, .betaD- 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	15 mg/m3	OSHA Z-1



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		dust)		
		TWA (respirable fraction)	5 mg/m3	OSHA Z-1
		TWA (Total dust)	15 mg/m3	OSHA P0
		TWA (respir- able dust fraction)	5 mg/m3	OSHA P0
Tocilizumab	375823-41-9	IOEL	0.4 mg/m3	Roche In- dustrial Hy- giene Com- mittee (RIHC)

Engineering measures : No data available

Personal protective equipment

Respiratory protection : No personal respiratory protective equipment normally requi-

red.

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 : Handle in accordance with good industrial hygiene and safety

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



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Melting point/range : No data available

Boiling point/boiling range : No data available

Flash point : does not flash

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

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

SECTION 10. STABILITY AND REACTIVITY

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

Chemical stability : Stable under normal conditions.

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

Does not contain any antimicrobial preservative; therefore, care must be taken to ensure the sterility of the prepared solu-

tion



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Possibility of hazardous reac-

tions

Stable under recommended storage conditions.

No hazards to be specially mentioned.

Incompatible materials : No data available

Hazardous decomposition

products

: No data available

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity

Not classified based on available information.

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 based on available information.

Serious eye damage/eye irritation

Not classified based on available information.

Respiratory or skin sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Germ cell mutagenicity

Not classified based on available information.

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 based on available information.



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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.

OSHANo 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 based on available information.

STOT-single exposure

Not classified based on available information.

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 based on available information.

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 : mg/kg bw/day, 10

Application Route : i.v. Exposure time : 28 d

Remarks : Subacute toxicity

Aspiration toxicity

Not classified based on available information.

Components:

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

No data available



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Further information

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

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: ves

Remarks: nominal concentration

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

Exposure time: 48 h



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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:



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Ozone-Depletion Potential : Regulation: 40 CFR Protection of Environment; Part 82 Pro-

tection 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).

Components:

Tocilizumab:

Additional ecological infor-

mation

No data available

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. Do not re-use empty containers.

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 Annex II of MARPOL 73/78 and the IBC Code

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



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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 monohydro- 10039-32-4 >= 0.1 - < 1 %

gen phosphate, dodeca-

hydrate

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

di Sodium monohydro- 10039-32-4 >= 0.1 - < 1 %

gen phosphate, dodeca-

hydrate

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



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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:

AIIC : Not in compliance with the inventory

DSL : This product contains the following components that are not

on the Canadian DSL nor NDSL.

Tocilizumab

NZIoC : On the inventory, or in compliance with the inventory

ENCS : Not in compliance with the inventory

ISHL : Not in compliance with the inventory

KECI : Not in compliance with the inventory

PICCS : Not in compliance with the inventory

IECSC : Not in compliance with the inventory

TCSI : Not in compliance with the inventory

TSCA : Product contains substance(s) not listed on TSCA inventory.

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

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NFPA 704:

Health 0 0 Instability

Special hazard

HMIS® IV:



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 PO : USA. Table Z-1-A Limits for Air Contaminants (1989 vacated

values)

OSHA Z-1 : USA. Occupational Exposure Limits (OSHA) - Table Z-1 Lim-

its 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 Standardisation; 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 Organisation 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



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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, Authorisation 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

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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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