

# SAFETY DATA SHEET

**Genentech**  
A Member of the Roche Group

## HEMLIBRA Vials 12mg/0.4ml

Version  
1.0

Revision Date:  
06/19/2025

Date of last issue: -  
Date of first issue: 06/19/2025

### SECTION 1. IDENTIFICATION

Product name : HEMLIBRA Vials 12mg/0.4ml

Product code : RO553-4262/F08-00

Common name(s),  
synonym(s) of the substance : Emicizumab with excipients in aqueous solution

#### 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 : Laboratory chemicals  
Refer to product literature for further details.  
Formulated pharmaceutical active substance

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### 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

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

#### Other hazards

None known.

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### SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

#### Components

Chemical name	CAS-No.	Concentration (% w/w)
Emicizumab	1610943-06-0	3
L-Arginine	74-79-3	2.61
L-Histidine	71-00-1	0.31
L-Aspartic acid	56-84-8	0
Ethylene oxide-propylene oxide triblock copolymer	691397-13-4	0.05

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Water

7732-18-5

94

**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)  
Carbon dioxide (CO2), carbon monoxide (CO), oxides of nitrogen (NOx), dense black smoke.

Further information : Standard procedure for chemical fires.  
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

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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, 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.

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**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

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**SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION****Ingredients with workplace control parameters**

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Emicizumab	1610943-06-0	IOEL	0.02 mg/m <sup>3</sup>	Roche Industrial Hygiene Committee (RIHC)

**Personal protective equipment**

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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	<p>In case of contact through splashing:</p> <p>: Nitrile rubber</p> <p>: &gt; 30 min</p> <p>: &gt; 0.11 mm</p>
Material	<p>In case of full contact:</p> <p>: butyl-rubber</p> <p>: &gt; 480 min</p> <p>: &gt; 0.4 mm</p>
Break through time	
Glove thickness	
Material	
Break through time	
Glove thickness	
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.

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## SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	: Aqueous solution, sterile
Color	: colorless
Odor	: No data available
Odor Threshold	: No data available
pH	: 6.0
Melting point/ range	: No data available
Boiling point/boiling range	: No data available

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Flash point : No data available  
Evaporation rate : No data available  
Self-ignition : Not applicable  
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

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

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solution

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

No data available

Incompatible materials : No data available

Not applicable

Hazardous decomposition products : No data available

No hazardous decomposition products are known.

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SECTION 11. TOXICOLOGICAL INFORMATION**Acute toxicity**

Not classified due to lack of data.

**Components:****Emicizumab:**

Acute oral toxicity : Remarks: Not bioavailable by oral administration

**L-Arginine:**

Acute oral toxicity : LD50 Oral (Rat, male and female): > 5,110 mg/kg

**Skin corrosion/irritation**

Not classified due to lack of data.

**Components:****L-Arginine:**

Species : Rabbit  
Method : OECD Test Guideline 404  
Result : No skin irritation  
GLP : no

**Serious eye damage/eye irritation**

Not classified due to lack of data.

**Components:****L-Arginine:**

Species : Rabbit  
Result : No eye irritation

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Method : OECD Test Guideline 405

**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:****L-Arginine:**

Genotoxicity in vitro : Test Type: reverse mutation assay  
Test system: *Salmonella typhimurium*  
Metabolic activation: with and without metabolic activation  
Method: OECD Test Guideline 471  
Result: negative

**Carcinogenicity**

Not classified due to lack of data.

**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.

**STOT-repeated exposure**

Not classified due to lack of data.

**Repeated dose toxicity****Components:****Emicizumab:**

Species : cynomolgus monkey  
NOAEL : 100 mg/kg/w  
Application Route : i.v.  
Exposure time : 4 Weeks

Species : cynomolgus monkey  
NOAEL : 30 mg/kg/w  
Application Route : s.c.  
Exposure time : 13 Weeks

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Species : cynomolgus monkey  
NOAEL : 30 mg/kg/w  
Application Route : s.c.  
Exposure time : 26 Weeks

**L-Arginine:**

Species : Rat, male  
NOAEL : 3,130.9 mg/kg  
Exposure time : 13 Weeks

**Aspiration toxicity**

Not classified due to lack of data.

**Further information****Product:**

Remarks : No data available

**Components:****Emicizumab:**

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

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**SECTION 12. ECOLOGICAL INFORMATION****Ecotoxicity****Components:****Emicizumab:**

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  
Remarks: nominal concentration

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 100 mg/l  
Exposure time: 48 h  
Method: OECD Test Guideline 202  
GLP: yes  
Remarks: nominal concentration

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

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Exposure time: 48 h  
Method: OECD Test Guideline 202  
GLP: yes  
Remarks: nominal concentration

Toxicity to algae/aquatic plants : ErC50 (Desmodesmus subspicatus (green algae)): > 100 mg/l

Exposure time: 72 h  
Method: OECD Test Guideline 201  
GLP: yes  
Remarks: nominal concentration

NOErC (Desmodesmus subspicatus (green algae)): 100 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201  
GLP: yes  
Remarks: nominal concentration

EyC50 (Desmodesmus subspicatus (green algae)): > 100 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201  
GLP: yes  
Remarks: nominal concentration

NOEyC (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): Exposure time: 14 d  
Method: OECD Test Guideline 301F  
GLP: yes  
Remarks: no adverse influence on substrate biodegradation

**L-Arginine:**

Toxicity to fish

: LC50 (Brachydanio rerio (zebrafish)): 2,800 mg/l  
Exposure time: 96 h  
Method: OECD Test Guideline 203  
GLP: yes

**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

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**Persistence and degradability****Components:****Emicizumab:**

Biodegradability : Result: Readily biodegradable.  
Biodegradation: 99 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301F  
GLP: yes

Physico-chemical removability : Method: OECD Test Guideline 301F  
Remarks: Not abiotically degradable

**L-Arginine:**

Biodegradability : Result: Readily biodegradable.

**Bioaccumulative potential****Components:****Emicizumab:**

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

**L-Arginine:**

Partition coefficient: n-octanol/water : log Pow: -4.2 (68 °F / 20 °C)

**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:****L-Arginine:**

Adsorbed organic bound halogens (AOX) : Remarks: Not applicable

Additional ecological information : No data available

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**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.

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**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

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**SECTION 15. REGULATORY INFORMATION****CERCLA Reportable Quantity**

This material does not contain any components with a CERCLA 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**

Components	CAS-No.	Component TPQ (lbs)
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**SARA 311/312 Hazards** : No SARA Hazards

**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).

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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**

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.

This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.

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****Pennsylvania Right To Know**

Water	7732-18-5
Emicizumab	1610943-06-0

**Maine Chemicals of High Concern****Vermont Chemicals of High Concern****Washington Chemicals of High Concern****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.  Emicizumab  Ethylene oxide-propylene oxide triblock copolymer
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.

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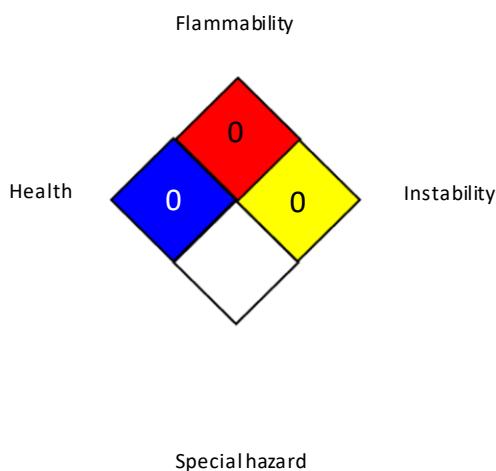
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No substances are subject to TSCA 12(b) export notification requirements.

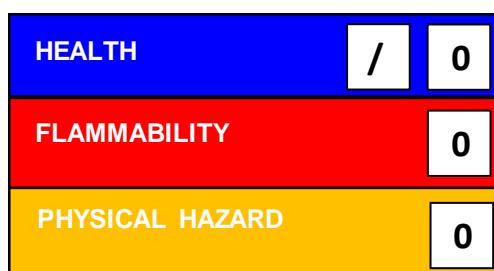
## SECTION 16. OTHER INFORMATION

## Further information

## NFPA 704:



## 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

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 of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS

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- 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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