

# SAFETY DATA SHEET

## HEMLIBRA Vials 12mg/0.4ml

Version 1.1                      Revision Date: 03-19-2020                      Date of last issue: 04-18-2019  
Date of first issue: 04-18-2019

### SECTION 1. IDENTIFICATION

Product name                      :   HEMLIBRA Vials 12mg/0.4ml  
Product code                      :   RO553-4262/F08  
Common name(s), syno-         :   Emicizumab with excipients in aqueous solution  
nym(s) of the substance

#### Manufacturer or supplier's details

Company name of supplier       :   F. Hoffmann-La Roche Ltd.

Address                            :  
P.O. BOX  
4070 Basel  
Switzerland

Telephone                         :   +41-61/688 54 80  
Telefax                            :   +41-61/681 72 76  
E-mail address                   :   info.sds@roche.com  
Emergency telephone  
Emergency telephone             :   +41-61/688 54 80  
number

#### Recommended use of the chemical and restrictions on use

Recommended use                 :   Formulated pharmaceutical active substance  
Restrictions on use               :   For professional users only.

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### SECTION 2. HAZARDS IDENTIFICATION

#### GHS classification in accordance with 29 CFR 1910.1200

Not a hazardous substance or mixture.

#### GHS label elements

Not a hazardous substance or mixture.

#### 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	3.0
L-Arginine	74-79-3	2.61
L-Histidine	71-00-1	0.31
L-Aspartic acid	56-84-8	0.0
Poloxamer 188	691397-13-4	0.05
Water	7732-18-5	> 94.0

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### 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.

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### SECTION 5. FIRE-FIGHTING MEASURES

- Suitable extinguishing media : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
- Specific hazards during fire fighting : No information available.
- Hazardous combustion products : In case of fire hazardous decomposition products may be produced such as:  
Carbon monoxide  
Nitrogen oxides (NO<sub>x</sub>)
- 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.

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### SECTION 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protection : Refer to protective measures listed in sections 7 and 8.

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tive equipment and emergency procedures

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.

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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.

Further information on storage 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 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)

**Engineering measures** : No data available

#### Personal protective equipment

Respiratory protection : No personal respiratory protective equipment normally required.

Hand protection

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Material : Protective gloves

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.

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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

Flash point : does not flash

Evaporation rate : No data available

Flammability (solid, gas) : Does not sustain combustion.

Flammability (liquids) : Does not sustain combustion.

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

Solubility(ies)  
Water solubility : completely miscible

Solubility in other solvents : No data available

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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 : The substance or mixture is not classified as oxidizing.

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### 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 solution

Possibility of hazardous reactions : Stable under recommended storage conditions.  
No hazards to be specially mentioned.

Conditions to avoid : No data available

Incompatible materials : No data available

Hazardous decomposition products : No data available

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### SECTION 11. TOXICOLOGICAL INFORMATION

#### Acute toxicity

Not classified based on available information.

#### Components:

##### **Emicizumab:**

Acute oral toxicity : Remarks: Not bioavailable by oral administration

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

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

**HEMLIBRA Vials 12mg/0.4ml**Version  
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Not classified based on available information.

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

Remarks : May cause skin irritation in susceptible persons.

**Serious eye damage/eye irritation**

Not classified based on available information.

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

Result : Irritating to eyes.

Remarks : May cause irreversible eye damage.

**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.

**Carcinogenicity**

Not classified based on available information.

**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 based on available information.

**STOT-single exposure**

Not classified based on available information.

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

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

**STOT-repeated exposure**

Not classified based on available information.

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

**Repeated dose toxicity****Components:****Emicizumab:**Species : cynomolgus monkey  
NOAEL : mg/kg/w, 100  
Application Route : i.v.  
Exposure time : 4 WeeksSpecies : cynomolgus monkey  
NOAEL : mg/kg/w, 30  
Application Route : s.c.  
Exposure time : 13 WeeksSpecies : cynomolgus monkey  
NOAEL : mg/kg/w, 30  
Application Route : s.c.  
Exposure time : 26 Weeks**Aspiration toxicity**

Not classified based on available information.

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

No data available

**Further information****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

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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  
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



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- NOEC (Brachydanio rerio (zebrafish)): 1,000 mg/l  
 Exposure time: 96 h  
 Method: OECD Test Guideline 203  
 GLP: yes
- Toxicity to daphnia and other aquatic invertebrates : NOEC (Daphnia magna (Water flea)): 1,000 mg/l  
 Exposure time: 24 h  
 Method: OECD Test Guideline 202  
 GLP: yes
- Toxicity to microorganisms : EC10 (Pseudomonas putida): < 10,000 mg/l  
 Exposure time: 16 h  
 Method: DIN 38 412 Part 8  
 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

**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

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

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

**L-Arginine:**

- Partition coefficient: n-octanol/water : log Pow: -4.2

**Mobility in soil**

No data available

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### 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).

#### 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.  
Do not re-use empty containers.

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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

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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).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCM 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

**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:**

DSL : This product contains the following components that are not on the Canadian DSL nor NDSL.

Emicizumab

Poloxamer 188

AICS : Not in compliance with the inventory

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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 : Substance(s) not listed on TSCA inventory

### TSCA list

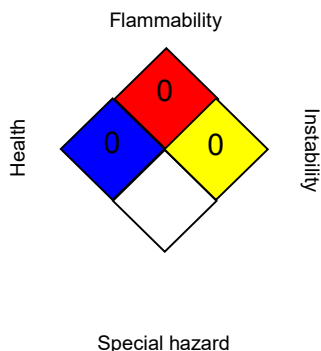
No substances are subject to a Significant New Use Rule.

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

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## SECTION 16. OTHER INFORMATION

### NFPA:



### HMIS® IV:

HEALTH	/	0
FLAMMABILITY		0
PHYSICAL HAZARD		0

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

AICS - Australian Inventory of Chemical Substances; 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

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- 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 - 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; 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 Material 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.

US / Z8 / 1810