

Safety Data Sheet

HEMLIBRA™ (60 mg/0.4 ml)

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product name	HEMLIBRA™ (60 mg/0.4 ml)	
Product code	SAP-10167387	
Roche number	RO5534262-000	*1
Synonyms	- ACE910 aqueous solution - Emicizumab-kxwh formulation (60 mg/0.4 ml)	

1.2. Relevant identified uses of the substance or mixture and uses advised against

Use	- pharmaceutical active substance	*1
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1.3. Details of the supplier of the safety data sheet

Company information	Enquiries: Genentech, Inc. 1 DNA Way South San Francisco USA-CA 94080 United States of America	Local representation:
	Phone 001-(650) 225-1000 E-Mail info.sds@roche.com US Chemtrec phone: (800)-424-9300	

1.4. Emergency telephone number

Emergency telephone number	US Chemtrec phone: (800)-424-9300
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*1 referring to: Emicizumab-kxwh

SECTION 2: Hazards identification

Classification of the substance or mixture / Label elements

GHS Classification	no classification and labelling according to GHS
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Other hazards

Note	- no information available
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SECTION 3: Composition/information on ingredients

Ingredients	Concentration	GHS-Classification (pure ingredient)
Emicizumab-kxwh 1610943-06-0	12.7 %	
L-Arginine 74-79-3	2.2 %	
*1 referring to:	Emicizumab-kxwh	

SECTION 4: First aid measures

4.1. Description of first aid measures

Eye contact	- rinse immediately with tap water for at least 20 minutes - open eyelids forcibly
Skin contact	- remove immediately contaminated clothes, wash affected skin with water and soap - do not use any solvents
Inhalation	- remove the casualty to fresh air - in the event of symptoms get medical treatment

4.2. Most important symptoms and effects, both acute and delayed

Note	- no information available
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4.3. Indication of any immediate medical attention and special treatment needed

Note to physician	- treat symptomatically
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SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	- adapt extinguishing media to surrounding fire conditions	
Flash point (liquid)	260 °C	*2

5.2. Special hazards arising from the substance or mixture

Specific hazards	- no particular hazards known
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5.3. Advice for firefighters

Protection of fire-fighters - precipitate gases/vapours/mists with water spray

*2 referring to: Poloxamer 188

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions - no special precautions required

6.2. Environmental precautions

Environmental protection - no special environmental precautions required

6.3. Methods and material for containment and cleaning up

Methods for cleaning up - collect spilled solutions with inert adsorbent and hand over to waste removal

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Technical measures - processing in closed systems, if possible superposed by inert gas (e.g. nitrogen)

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions - 2 - 8 °C

Packaging materials - vials

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Threshold value (Roche) air - IOEL (Internal Occupational Exposure Limit): 0.02 mg/m³ *1

8.2. Exposure controls

Respiratory protection - Respiratory protection is recommended as a precaution to minimize exposure. Effective engineering controls are considered to be the primary means to control worker exposure. Respiratory protection should not substitute for feasible engineering controls.
- in case of open handling or accidental release:
particle mask or respirator with independent air supply

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Hand protection - protective gloves (eg made of neoprene, nitrile or butyl rubber)

Eye protection - safety glasses

*1 referring to: Emicizumab-kxwh

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Color almost colorless

Form clear liquid

Molecular mass 145.637 kDa *1

Partition coefficient log P_{ow} -3.32 (octanol/water) *3
log P_{ow} -3.89 (octanol/water) *4

pH value 6.0

9.2. Other information

Note - no information available

*1 referring to: Emicizumab-kxwh

*3 referring to: L-Histidine

*4 referring to: L-Aspartic acid

SECTION 10: Stability and reactivity

10.1. Reactivity

Note - no information available

10.2. Chemical stability

Note - no information available

10.3. Possibility of hazardous reactions

Note - no information available

10.4. Conditions to avoid

Conditions to avoid - warming

10.5. Incompatible materials

Note - no information available

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10.6. Hazardous decomposition products

Note - no information available

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity	- not bioavailable by oral administration	*1
	- LD ₅₀ > 15'000 mg/kg (oral, rat)	*2
	- LD ₅₀ > 5'110 mg/kg (oral, rat)	*5
Subacute toxicity	- NOAEL 100 mg/kg/w (i.v., cynomolgus monkey, 4 weeks)	*1
Subchronic toxicity	- NOAEL 30 mg/kg/w (s.c., cynomolgus monkey; 13 weeks)	*1
Chronic toxicity	- NOAEL 30 mg/kg/w (s.c., cynomolgus monkey; 26 weeks)	*1
Local effects	- skin: non-irritant (rabbit; OECD No. 404)	*5
	- eye: not severe irritant or corrosive	*5
Sensitization	anaphylactic reactions may occur following the parenteral application of proteins; rare cases of hypersensitivity have been described with other monoclonal antibodies	*1
	- non-sensitizing (guinea pig)	*2
Mutagenicity	- negative, both with and without metabolic activation (in vitro test system; OECD No. 473 (Mammalian Cytogenic Test))	*5
Carcinogenicity	- no information available	
Reproductive toxicity	- no information available	
STOT-single exposure	- no information available	
STOT-repeated exposure	- no information available	
Aspiration hazard	- no information available	
*1 referring to:	Emicizumab-kxwh	
*2 referring to:	Poloxamer 188	
*5 referring to:	L-Arginine	

SECTION 12: Ecological information

12.1. Toxicity

Ecotoxicity	- barely toxic for algae (Desmodesmus (=Scenedesmus) subspicatus) ErC ₅₀ (72 h) > 100 mg/l (nominal concentration) EyC ₅₀ (72 h) > 100 mg/l (nominal concentration) NOErC (72 h) 100 mg/l (nominal concentration) NOEyC (72 h) 100 mg/l (nominal concentration) (OECD No. 201)	*1
	- barely toxic for planktonic crustaceans (Daphnia magna) EC ₅₀ (48 h) > 100 mg/l (nominal concentration) NOErC (48 h) 100 mg/l (nominal concentration) (OECD No. 202)	*1
	- barely toxic for fish (zebrafish) EC ₅₀ (96 h) > 100 mg/l (nominal concentration) NOEC (96 h) 100 mg/l (nominal concentration) (OECD No. 203)	*1

12.2. Persistence and degradability

Ready biodegradability	- readily biodegradable 99 % BOD/ThOD, 28 (Manometric Respirometry Test, OECD No. 301 F)	*1
Abiotic degradation	- not abiotically degradable ; Oxitop (Manometric respirometry test, OECD no. 301 F, abiotic control)	*1

12.3. Bioaccumulative potential

Note - no information available

12.4. Mobility in soil

Note - no information available

12.5. Results of PBT and vPvB assessment

Note - no information available

12.6. Other adverse effects

Note - no information available

*1 referring to: Emicizumab-kxwh

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SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste from residues - observe local/national regulations regarding waste disposal

SECTION 14: Transport information

Note - not classified as Dangerous Good according to the Dangerous Goods Regulations, proper shipping name non-regulated

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

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 and to local officials.
- State and local regulations vary and may impose additional reporting requirements.

SECTION 16: Other information

Note - Please note this Safety Data Sheet for the bulk product does not apply for the finished, packaged medicinal product intended for the final user.

Edition documentation - changes from previous version in sections 6, 8

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.