

Safety Data Sheet

# HEMLIBRA™ (30 mg/1.0 ml)

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

### 1.1. Product identifier

Product name	HEMLIBRA™ (30 mg/1.0 ml)	
Product code	SAP-10168799	
Roche number	RO5534262-000	*1
Synonyms	- ACE910 aqueous solution - Emicizumab-kxwh formulation (30 mg/1.0 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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# HEMLIBRAT<sup>TM</sup> (30 mg/1.0 ml)

## SECTION 3: Composition/information on ingredients

Ingredients	Concentration	GHS-Classification (pure ingredient)
Emicizumab-kxwh 1610943-06-0	2.8 %	
*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
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*2 referring to:	Poloxamer 188
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## 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/m<sup>3</sup> \*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

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

Eye protection - safety glasses

\*1 referring to: Emicizumab-kxwh

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## 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 <sub>ow</sub> -3.32 (octanol/water)	*3
	log P <sub>ow</sub> -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

### 10.6. Hazardous decomposition products

Note - no information available

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## SECTION 11: Toxicological information

### 11.1. Information on toxicological effects

Acute toxicity	- not bioavailable by oral administration	*1
	- LD <sub>50</sub> > 15'000 mg/kg (oral, rat)	*2
	- LD <sub>50</sub> > 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 <sub>50</sub> (72 h) > 100 mg/l (nominal concentration) EyC <sub>50</sub> (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 <sub>50</sub> (48 h) > 100 mg/l (nominal concentration) NOErC (48 h) 100 mg/l (nominal concentration) (OECD No. 202)	*1

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- barely toxic for fish (zebrafish)  
EC<sub>50</sub> (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

## 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

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### 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.