Safety Data Sheet

HEMLIBRA™ (105 mg/0.7 ml)

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

1.1. Product identifier

Product name	HEMLIBRA™ (105 mg/0.7 ml)	
Product code	SAP-10168797	
Roche number	RO5534262-000	*1
Synonyms	- ACE910 aqueous solution - Emicizumab-kxwh formulation (105 mg/0.7 ml)	

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

Use	- pharmaceutical active substance	*1

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

Phone 001-(650) 225-1000
E-Mail info.sds@roche.com
US Chemtrec phone:
(800)-424-9300

Local representation:

1.4. Emergency telephone number

Emergency telephone number: US Chemtrec phone: (800)-424-9300

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

Other hazards

Note: - no information available

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

4.3. Indication of any immediate medical attention and special treatment needed

Note to physician	- treat symptomatically

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

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

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

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

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.