# Safety Data Sheet

**HEMLIBRA™ (150 mg/1.0 ml)**

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

### 1.1. Product identifier

<table>
<thead>
<tr>
<th><strong>Product name</strong></th>
<th>HEMLIBRA™ (150 mg/1.0 ml)</th>
</tr>
</thead>
</table>

**Product code**  SAP-10168796

**Roche number**  RO5534262-000

**Synonyms**
- ACE910 aqueous solution
- Emicizumab-kxwh formulation (150 mg/1.0 ml)

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

**Use**
- Pharmaceutical active substance

### 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

### 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

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>Concentration</th>
<th>GHS-Classification (pure ingredient)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Emicizumab-kxwh</td>
<td>12.7 %</td>
<td></td>
</tr>
<tr>
<td>1610943-06-0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>L-Arginine</td>
<td>2.2 %</td>
<td></td>
</tr>
<tr>
<td>74-79-3</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*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

Note 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

### 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)
SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Color</td>
<td>almost colorless</td>
</tr>
<tr>
<td>Form</td>
<td>clear liquid</td>
</tr>
<tr>
<td>Molecular mass</td>
<td>145.637 kDa</td>
</tr>
<tr>
<td>Partition coefficient</td>
<td>( \log P_{ow} -3.32 ) (octanol/water)</td>
</tr>
<tr>
<td></td>
<td>( \log P_{ow} -3.89 ) (octanol/water)</td>
</tr>
<tr>
<td>pH value</td>
<td>6.0</td>
</tr>
</tbody>
</table>

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
- LD$_{50}$ > 15'000 mg/kg (oral, rat) *1
- 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
### 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)

- 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)

- 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)

### 12.2. Persistence and degradability

Ready biodegradability
- readily biodegradable
  - 99 % BOD/ThOD, 28
    - Manometric Respirometry Test, OECD No. 301 F)

Abiotic degradation
- not abiotically degradable ; Oxitop
  - Manometric respirometry test, OECD no. 301 F, abiotic control

### 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.