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
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

1.3. 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

*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
HEMLIBRA™ (105 mg/0.7 ml)

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

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

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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

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**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

<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

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

*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\textsubscript{50} (72 h) > 100 mg/l (nominal concentration)
  EyC\textsubscript{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)
- barely toxic for planktonic crustaceans (Daphnia magna)
  EC\textsubscript{50} (48 h) > 100 mg/l (nominal concentration)
  NOErC (48 h)  100 mg/l (nominal concentration)
  (OECD No. 202)
- barely toxic for fish (zebrafish)
  EC\textsubscript{50} (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
### 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.