# 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
- **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

### 1.3. Details of the supplier of the safety data sheet

- **Company information**: 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

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

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
- \( \text{LD}_{50} > 15'000 \text{ mg/kg} \) (oral, rat) \(^1\)
- \( \text{LD}_{50} > 5'110 \text{ mg/kg} \) (oral, rat) \(^2\)

**Subacute toxicity**
- \( \text{NOAEL} 100 \text{ mg/kg/w} \) (i.v., cynomolgus monkey, 4 weeks) \(^1\)

**Subchronic toxicity**
- \( \text{NOAEL} 30 \text{ mg/kg/w} \) (s.c., cynomolgus monkey; 13 weeks) \(^1\)

**Chronic toxicity**
- \( \text{NOAEL} 30 \text{ mg/kg/w} \) (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)
              ErC50 (72 h) > 100 mg/l (nominal concentration)
              EyC50 (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)
                EC50 (48 h) > 100 mg/l (nominal concentration)
                NOErc (48 h) 100 mg/l (nominal concentration)
                (OECD No. 202)

              - barely toxic for fish (zebrafish)
                EC50 (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)
                          (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
HEMLIBRAM (60 mg/0.4 ml)

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.