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
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

1.3. 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>2.8 %</td>
<td></td>
</tr>
<tr>
<td>1610943-06-0</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

<table>
<thead>
<tr>
<th>Threshold value (Roche) air</th>
<th>IOEL (Internal Occupational Exposure Limit): 0.02 mg/m³</th>
</tr>
</thead>
</table>

#### 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. |
| 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

Acute toxicity
- not bioavailable by oral administration
- \( \text{LD}_{50} > 15'000 \) mg/kg (oral, rat) \(^1\)
- \( \text{LD}_{50} > 5'110 \) 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)
- \( \text{ErC}_{50} (72 \text{ h}) > 100 \) mg/l (nominal concentration)
- \( \text{EyC}_{50} (72 \text{ h}) > 100 \) mg/l (nominal concentration)
- \( \text{NOErC} (72 \text{ h}) 100 \) mg/l (nominal concentration)
- \( \text{NOEyC} (72 \text{ h}) 100 \) mg/l (nominal concentration)
- OECD No. 201

- barely toxic for planktonic crustaceans (Daphnia magna)
- \( \text{EC}_{50} (48 \text{ h}) > 100 \) mg/l (nominal concentration)
- \( \text{NOErC} (48 \text{ h}) 100 \) mg/l (nominal concentration)
- OECD No. 202

\(^{1}\) referring to: Emicizumab-kxwh
HEMLIBRA™ (30 mg/1.0 ml)

- barely toxic for fish (zebrafish)
  EC50 (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.