# Safety Data Sheet

## XOLAIR(R) PFS (150 mg)

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

#### 1.1. Product identifier

<table>
<thead>
<tr>
<th>Product name</th>
<th>XOLAIR(R) PFS (150 mg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product code</td>
<td>RO548-9789-F04</td>
</tr>
<tr>
<td>Synonyms</td>
<td>XOLAIR® Prefilled Syringes 150 mg/ml</td>
</tr>
</tbody>
</table>

#### 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

<table>
<thead>
<tr>
<th>Company information</th>
<th>Enquiries: Genentech, Inc.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1 DNA Way</td>
</tr>
<tr>
<td></td>
<td>South San Francisco</td>
</tr>
<tr>
<td></td>
<td>USA-CA 94080</td>
</tr>
<tr>
<td></td>
<td>United States of America</td>
</tr>
<tr>
<td></td>
<td>Phone 001-(650) 225-1000</td>
</tr>
<tr>
<td></td>
<td>E-Mail <a href="mailto:info.sds@roche.com">info.sds@roche.com</a></td>
</tr>
<tr>
<td></td>
<td>US Chemtrec phone: (800)-424-9300</td>
</tr>
</tbody>
</table>

#### 1.4. Emergency telephone number

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

*1 referring to: Omalizumab

### 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 |

Date: 10.9.18/LS (SEISMO) Replacing edition of: -- Page: 1/7
SECTION 3: Composition/information on ingredients

Characterization
Xolair Drug Product: Sterile Liquid for injection (s.c.) recombinant humanized monoclonal antibody *1

Ingredients

<table>
<thead>
<tr>
<th>Concentration</th>
<th>GHS-Classification (pure ingredient)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Omalizumab</td>
<td>12 %</td>
</tr>
</tbody>
</table>

*1 referring to: Omalizumab

SECTION 4: First aid measures

4.1. Description of first aid measures

Eye contact
- rinse with tap water for 20 minutes - open eyelids forcibly

Skin contact
- remove immediately contaminated clothes, wash affected skin with plenty of water

Inhalation
- remove the casualty to fresh air and keep him/her calm
- 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
- water spray jet, dry powder, foam, carbon dioxide, adapt extinguishing media to surrounding fire conditions

Flash point (liquid)
not applicable

5.2. Special hazards arising from the substance or mixture

Specific hazards
- formation of toxic combustion gases (ammonia, sulfur oxides, nitrogen oxides) possible

5.3. Advice for firefighters

Protection of fire-fighters
- precipitate gases/vapours/mists with water spray
**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 liquids by means of sand, earth or another suitable material

**SECTION 7: Handling and storage**

**7.1. Precautions for safe handling**

Suitable materials  -  glass

**7.2. Conditions for safe storage, including any incompatibilities**

Storage conditions  -  2 - 8 °C
-  protected from light

Validity  -  see expiry date on the label
-  8 h, 2 to 8 °C  
-  4 h, at room temperature  

Packaging materials  -  prefilled syringes

*2 referring to: XOLAIR reconstituted solution

**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.
-  respiratory protection not necessary during normal operations
Hand protection - protective gloves (eg made of neoprene, nitrile or butyl rubber)
Eye protection - safety glasses

*1 referring to: Omalizumab

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Color colorless, clear
clear to opalescent
Form sterile liquid
Molecular mass ~ 149 kDa
*pH value 6.0

9.2. Other information

Note - no information available

*1 referring to: Omalizumab

SECTION 10: Stability and reactivity

10.1. Reactivity

Note - no information available

10.2. Chemical stability

Stability - does not contain any antimicrobial preservative; therefore, care must be taken to ensure the sterility of the prepared solution - as for all other proteins, monoclonal antibodies are temperature-sensitive; the thermal denaturation has an impact on quality but does not affect Plant and Process Safety; during decomposition no flammable gas, no organic peroxide and no oxidising substances are created

*1

10.3. Possibility of hazardous reactions

Note - no information available

10.4. Conditions to avoid

Conditions to avoid - light - warming
### SECTION 11: Toxicological information

#### 11.1. Information on toxicological effects

<table>
<thead>
<tr>
<th>Category</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute toxicity</td>
<td>- not bioavailable by oral administration *1</td>
</tr>
<tr>
<td>Local effects</td>
<td>- no information available</td>
</tr>
<tr>
<td>Sensitization</td>
<td>anaphylactic reactions may occur following the intravenous application of proteins; rare cases of hypersensitivity have been described *1</td>
</tr>
<tr>
<td>Mutagenicity</td>
<td>- not mutagenic (Ames test, without and with metabolic activation) *1</td>
</tr>
<tr>
<td>Carcinogenicity</td>
<td>- no information available</td>
</tr>
<tr>
<td>Reproductive toxicity</td>
<td>- no information available</td>
</tr>
<tr>
<td>STOT-single exposure</td>
<td>- no information available</td>
</tr>
<tr>
<td>STOT-repeated exposure</td>
<td>- no information available</td>
</tr>
<tr>
<td>Aspiration hazard</td>
<td>- no information available</td>
</tr>
<tr>
<td>Potential Health Effects</td>
<td>- Exposure: Inhalation, Ingestion, Skin contact, Eye contact</td>
</tr>
<tr>
<td></td>
<td>- Carcinogenicity: not listed by NTP, IARC or OSHA</td>
</tr>
</tbody>
</table>

*1 referring to: Omalizumab

### SECTION 12: Ecological information

#### 12.1. Toxicity

<table>
<thead>
<tr>
<th>Ecotoxicity</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>- monoclonal antibodies are proteins with highly specific affinity to a certain antigen; therefore, no appreciable ecotoxic potential is to be expected *1</td>
</tr>
</tbody>
</table>

*1 referring to: Omalizumab
12.2. Persistence and degradability

Ready biodegradability - globular proteins are generally well biodegradable *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

PBT/vPvB - not PBT, not vPvB

12.6. Other adverse effects

Note - no information available

*1 referring to: Omalizumab

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste from residues - observe local/national regulations regarding waste disposal
- drain very small quantities into wastewater treatment plant

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

<table>
<thead>
<tr>
<th>Note</th>
<th>none</th>
</tr>
</thead>
<tbody>
<tr>
<td>Edition documentation</td>
<td>first edition</td>
</tr>
</tbody>
</table>

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.