### 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 (75 mg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product code</td>
<td>RO548-9789-F03</td>
</tr>
<tr>
<td>Synonyms</td>
<td>XOLAIR® Prefilled Syringes 75 mg/0.5 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>
</tbody>
</table>

Local representation:

US Chemtrec phone: (800)-424-9300

### 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
XOLAIR(R) PFS (75 mg)

SECTION 3: Composition/information on ingredients

<table>
<thead>
<tr>
<th>Characterization</th>
<th>Xolair Drug Product: Sterile Liquid for injection (s.c.) recombinant humanized monoclonal antibody</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ingredients</td>
<td>Concentration</td>
</tr>
<tr>
<td>Omalizumab</td>
<td>242138-07-4</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
Special method of fire-fighting - if possible precipitate fire gases with a water jet

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

Packaging materials - prefilled syringes

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 *1

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
10.5. Incompatible materials

Note - no information available

10.6. Hazardous decomposition products

Note - no information available

*1 referring to: Omalizumab

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity - not bioavailable by oral administration *1

Local effects - no information available

Sensitization anaphylactic reactions may occur following the intravenous application of proteins; rare cases of hypersensitivity have been described *1

Mutagenicity - not mutagenic (Ames test, without and with metabolic activation) *1

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

Potential Health Effects - Exposure: Inhalation, Ingestion, Skin contact, Eye contact

- Carcinogenicity: not listed by NTP, IARC or OSHA

*1 referring to: Omalizumab

SECTION 12: Ecological information

12.1. Toxicity

Ecotoxicity - monoclonal antibodies are proteins with highly specific affinity to a certain antigen; therefore, no appreciable ecotoxic potential is to be expected *1
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.