

Safety Data Sheet

# XOLAIR(R) PFS (75 mg)

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

### 1.1. Product identifier

Product name XOLAIR(R) PFS (75 mg)  
 Product code RO548-9789-F03  
 Synonyms - XOLAIR® Prefilled Syringes 75 mg/0.5 ml

### 1.2. Relevant identified uses of the substance or mixture and uses advised against

Use - pharmaceutical active substance \*1

### 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	Local representation:
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### 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

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### SECTION 3: Composition/information on ingredients

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

Ingredients	Concentration	GHS-Classification (pure ingredient)
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Omalizumab 242138-07-4	12 %	
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\*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
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Flash point (liquid)	not applicable
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#### 5.2. Special hazards arising from the substance or mixture

Specific hazards	- formation of toxic combustion gases (ammonia, sulfur oxides, nitrogen oxides) possible
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#### 5.3. Advice for firefighters

Protection of fire-fighters	- precipitate gases/vapours/mists with water spray
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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/m<sup>3</sup> \*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.  
- respiratory protection not necessary during normal operations

Hand protection - protective gloves (eg made of neoprene, nitrile or butyl rubber)

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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

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### 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

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### 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.

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### SECTION 16: Other information

Note	- none
Edition documentation	- first edition

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.