

Safety Data Sheet

XOLAIR(R) PFS (150 mg)

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

1.1. Product identifier

Product name XOLAIR(R) PFS (150 mg)
 Product code RO548-9789-F04
 Synonyms - XOLAIR® Prefilled Syringes 150 mg/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

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

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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
- 8 h, 2 to 8 °C *2
- 4 h, at room temperature *2

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 *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

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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

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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.