SAFETY DATA SHEET

XOLAIR(R) PFS (150 mg)

SECTION 1. IDENTIFICATION

Product name : XOLAIR(R) PFS (150 mg)
Product code : RO548-9789/F04
Common name(s), synonym(s) of the substance : XOLAIR 15% aqueous solution of Omalizumab with excipients for XOLAIR Sterile Liquid for injection
XOLAIR 15% aqueous solution of Omalizumab with excipients for XOLAIR PFS

Manufacturer or supplier's details
Company name of supplier : Genentech, Inc.
Address : DNA Way 1
94080 South San Francisco
CA
USA
Telephone : 001-(650) 225-1000
E-mail address : info.sds@roche.com
Emergency telephone : US Chemtrec phone (800)-424-9300

Recommended use of the chemical and restrictions on use
Recommended use : Formulated pharmaceutical active substance
Restrictions on use : For professional users only.

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with 29 CFR 1910.1200
Not a hazardous substance or mixture.

GHS label elements
Not a hazardous substance or mixture.

Other hazards
None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Omalizumab</td>
<td>242138-07-4</td>
<td>15.0</td>
</tr>
<tr>
<td>L-Arginine, hydrochloride (1:1)</td>
<td>1119-34-2</td>
<td>4.21</td>
</tr>
<tr>
<td>L-Histidine monohydrochloride monohydrate</td>
<td>5934-29-2</td>
<td>0.23</td>
</tr>
<tr>
<td>L-Histidine</td>
<td>71-00-1</td>
<td>0.14</td>
</tr>
</tbody>
</table>
SECTION 4. FIRST AID MEASURES

General advice : Do not leave the victim unattended.

If inhaled : Move to fresh air.
             If unconscious, place in recovery position and seek medical advice.
             If symptoms persist, call a physician.

In case of skin contact : If on skin, rinse well with water.

In case of eye contact : Immediately flush eye(s) with plenty of water.
                        Remove contact lenses.
                        Protect unharmed eye.
                        If eye irritation persists, consult a specialist.

If swallowed : Keep respiratory tract clear.
                Do not give milk or alcoholic beverages.
                Never give anything by mouth to an unconscious person.
                If symptoms persist, call a physician.
                Rinse mouth with water.

Most important symptoms and effects, both acute and delayed : None known.

Notes to physician : The first aid procedure should be established in consultation with the doctor responsible for industrial medicine.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Specific hazards during fire fighting : No information available.

Hazardous combustion products : In case of fire hazardous decomposition products may be produced such as:
                                 Carbon monoxide
                                 Nitrogen oxides (NOx)
                                 Sulfur oxides

Further information : Standard procedure for chemical fires.
                     Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Special protective equipment for fire-fighters : Wear self-contained breathing apparatus for firefighting if necessary.
SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures: Refer to protective measures listed in sections 7 and 8.

Environmental precautions: Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for containment and cleaning up: Wipe up with absorbent material (e.g. cloth, fleece). Keep in suitable, closed containers for disposal.

SECTION 7. HANDLING AND STORAGE

Advice on protection against fire and explosion: Normal measures for preventive fire protection.

Advice on safe handling: For personal protection see section 8. Smoking, eating and drinking should be prohibited in the application area.

Conditions for safe storage: Electrical installations / working materials must comply with the technological safety standards.

Further information on storage conditions: See label, package insert or internal guidelines.

Materials to avoid: No materials to be especially mentioned.

Storage temperature: Protected from heat and light.

Further information on storage stability: No decomposition if stored and applied as directed.

Packaging material: Suitable material: glass, glass bottles, Prefilled syringes.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Omalizumab</td>
<td>242138-07-4</td>
<td>IOEL</td>
<td>0.02 mg/m3</td>
<td>Roche Industrial Hygiene Committee (RIHC)</td>
</tr>
</tbody>
</table>

Engineering measures: No data available.

Personal protective equipment

Respiratory protection: No personal respiratory protective equipment normally required.
### Hand protection

<table>
<thead>
<tr>
<th>Material</th>
<th>Protective gloves</th>
</tr>
</thead>
<tbody>
<tr>
<td>Remarks</td>
<td>Wear appropriate protective gloves to prevent skin contact. Replace torn or punctured gloves promptly.</td>
</tr>
<tr>
<td>Eye protection</td>
<td>Safety glasses</td>
</tr>
<tr>
<td>Skin and body protection</td>
<td>Protective suit</td>
</tr>
<tr>
<td>Hygiene measures</td>
<td>Handle in accordance with good industrial hygiene and safety practice.</td>
</tr>
</tbody>
</table>

### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>Aqueous solution, Clear liquid, sterile</td>
</tr>
<tr>
<td>Color</td>
<td>No data available</td>
</tr>
<tr>
<td>Odor</td>
<td>No data available</td>
</tr>
<tr>
<td>Odor Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>6.0</td>
</tr>
<tr>
<td>Melting point/range</td>
<td>No data available</td>
</tr>
<tr>
<td>Boiling point/boiling range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>does not flash</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Does not sustain combustion.</td>
</tr>
<tr>
<td>Flammability (liquids)</td>
<td>Does not sustain combustion.</td>
</tr>
<tr>
<td>Self-ignition</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapor pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapor density</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td></td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET

XOLAIR(R) PFS (150 mg)

Water solubility: completely miscible
Solubility in other solvents: No data available
Partition coefficient: n-octanol/water: No data available
Autoignition temperature: No data available
Decomposition temperature: No data available
Viscosity
  Viscosity, dynamic: No data available
  Viscosity, kinematic: No data available
Explosive properties: No data available
Oxidizing properties: No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity: No dangerous reaction known under conditions of normal use.
Chemical stability: Stable under normal conditions.
Proteins 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
Possibility of hazardous reactions: Stable under recommended storage conditions.
No hazards to be specially mentioned.
Conditions to avoid: No data available
Incompatible materials: No data available
Hazardous decomposition products: No data available

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity
Not classified based on available information.
Components:
Omalizumab:
Acute oral toxicity: Remarks: Not bioavailable by oral administration
Acute toxicity (other routes of administration): LD0 (Monkey): 200 mg/kg Application Route: i.v.
Skin corrosion/irritation
Not classified based on available information.

Serious eye damage/eye irritation
Not classified based on available information.

Respiratory or skin sensitization

Skin sensitization
Not classified based on available information.

Respiratory sensitization
Not classified based on available information.

Germ cell mutagenicity
Not classified based on available information.

Components:

Omalizumab:
Genotoxicity in vitro: Test Type: Ames test
Test system: Salmonella typhimurium
Metabolic activation: with and without metabolic activation
Result: negative

Carcinogenicity
Not classified based on available information.

IARC
No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA
No component of this product present at levels greater than or equal to 0.1% is on OSHA’s list of regulated carcinogens.

NTP
No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity
Not classified based on available information.

Components:

Omalizumab:
Effects on fetal development: Species: cynomolgus monkey, female
Application Route: s.c.
General Toxicity Maternal: NOAEL: 75 mg/kg bw/day
Embryo-fetal toxicity: NOAEL: 75 mg/kg bw/day
Result: No adverse effects.

STOT-single exposure
Not classified based on available information.

STOT-repeated exposure
Not classified based on available information.
Repeated dose toxicity

**Components:**

**Omalizumab:**
- Species: cynomolgus monkey
- LOEL: 30 mg/kg/w
- Application Route: s.c.
- Exposure time: 26 Weeks

Aspiration toxicity

Not classified based on available information.

Further information

**Components:**

**Omalizumab:**
- Remarks: anaphylactic reactions may occur following the intravenous application of proteins; rare cases of hypersensitivity have been described with other monoclonal antibodies

### SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

No data available

Persistence and degradability

**Components:**

**Omalizumab:**
- Biodegradability: Result: Globular proteins are generally well biodegradable

Bioaccumulative potential

**Components:**

**Omalizumab:**
- Partition coefficient: n-octanol/water: Remarks: No data available

Mobility in soil

No data available

Other adverse effects

**Product:**
- Ozone-Depletion Potential: Regulation: 40 CFR Protection of Environment; Part 82 Protection of Stratospheric Ozone - CAA Section 602 Class I Substances
- Remarks: This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).
Components:

Omalizumab:
Additional ecological information: Monoclonal antibodies are proteins with highly specific affinity to a certain antigen; therefore, no appreciable ecotoxic potential is to be expected

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods
Waste from residues: Can be disposed as waste water, when in compliance with local regulations.
Contaminated packaging: Empty containers should be taken to an approved waste handling site for recycling or disposal. Do not re-use empty containers.

SECTION 14. TRANSPORT INFORMATION

International Regulations
UNRTDG
Not regulated as a dangerous good
IATA-DGR
Not regulated as a dangerous good
IMDG-Code
Not regulated as a dangerous good
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable
Domestic regulation
49 CFR
Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION

EPCRA - Emergency Planning and Community Right-to-Know

CERCLA Reportable Quantity
This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity
This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Component TPQ (lbs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>SARA 311/312 Hazards</td>
<td>No SARA Hazards</td>
<td></td>
</tr>
</tbody>
</table>

8 / 11
Clean Air Act
This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App. A + B).
This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 112 (40 CFR 61).
This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).
This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCM Intermediate or Final VOC's (40 CFR 60.489).

Clean Water Act
This product does not contain any Hazardous Substances listed under the U.S. Clean Water Act, Section 311, Table 116.4A.
This product does not contain any Hazardous Chemicals listed under the U.S. Clean Water Act, Section 311, Table 117.3.
This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

US State Regulations
Massachusetts Right To Know
Pennsylvania Right To Know
Water 7732-18-5
Omalizumab 242138-07-4
L-Arginine, hydrochloride (1:1) 1119-34-2

Maine Chemicals of High Concern
Vermont Chemicals of High Concern
Washington Chemicals of High Concern

The ingredients of this product are reported in the following inventories:

DSL : This product contains the following components that are not on the Canadian DSL nor NDSL.
Omalizumab
L-Histidine monohydrochloride monohydrate

AICS : Not in compliance with the inventory
NZIoC : On the inventory, or in compliance with the inventory
ENCS : Not in compliance with the inventory
ISHL : Not in compliance with the inventory
KECI : Not in compliance with the inventory
PICCS : Not in compliance with the inventory
IECSC : Not in compliance with the inventory
TCSI : Not in compliance with the inventory
TSCA list
No substances are subject to a Significant New Use Rule. No substances are subject to TSCA 12(b) export notification requirements.

SECTION 16. OTHER INFORMATION

NFPA:

HMIS® IV:

Full text of other abbreviations

AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic sub-
**SAFETY DATA SHEET**

**XOLAIR(R) PFS (150 mg)**

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>Date of last issue:</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.0</td>
<td>01-30-2020</td>
<td>-</td>
</tr>
</tbody>
</table>

stance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

**Revision Date** : 01-30-2020

The information provided in this Material Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

US / Z8 / 1810