

Safety Data Sheet

XOLAIR(R) Vials (150 mg)

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

1.1. Product identifier

Product name XOLAIR(R) Vials (150 mg)

Product code CSE-3062

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

SECTION 3: Composition/information on ingredients

Characterization recombinant humanized monoclonal antibody *1

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Ingredients	Concentration
Omalizumab CAS: 242138-07-4	~ 57 %
Sucrose CAS: 57-50-1	~ 41 %
*1 referring to:	Omalizumab
SECTION 4: First aid measures	
4.1. Description of first aid measures	
Eye contact	- rinse with tap water for 10 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

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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

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

Packaging materials - vials

*2 referring to: XOLAIR reconstituted solution

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Threshold value (USA) air - ACGIH-TLV: 10 mg/m³ (not classifiable as a human carcinogen) *3
- OSHA-PEL: 5 mg/m³ (respirable fraction) *3
- OSHA-PEL: 15 mg/m³ (total dust) *3

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

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

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Eye protection - safety glasses

*1 referring to: Omalizumab

*3 referring to: Sucrose

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Color colorless, clear
clear to opalescent

Form clear 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

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

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

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12.5. Results of PBT and vPvB assessment

Note - no information available

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

SECTION 14: Transport information

Note - not classified by transport 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 (1-609-292-5560) and to local officials.
- State and local regulations vary and may impose additional reporting requirements.

SECTION 16: Other information

Note - Please note this Safety Data Sheet for the bulk product does not apply for the finished, packaged medicinal product intended for the final user.

Edition documentation - changes from previous version in sections 5, 6, 7, 8, 10, 11, 16

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.