**Material Safety Data Sheet**

# XOLAIR(R)

## 1. Product and Company Identification

| | |
|---|---|
| Product name | XOLAIR(R) |
| Product code | CSE-3062 |
| Company information | Enquiries:<br>Hoffmann-La Roche Inc.<br>340 Kingsland Street<br>USA-Nutley, N.J. 07110-1199<br>United States of America<br><br>Phone 001-973/235 50 00<br>E-Mail info.sds@roche.com<br><br>US Emergency phone: (800)-827-6243<br>US Chemtrec phone: (800)-424-9300 |

## 2. Hazard identification

**Emergency Overview**

| | |
|---|---|
| Form | clear liquid |
| Color | colorless, clear<br>clear to opalescent |
| Hazard Overview | - May cause allergic respiratory reactions. |
| Potential Health Effects | - Exposure: Inhalation, Ingestion, Skin contact, Eye contact<br>- Target Organs: skin, Central nervous system, Immune System, Skeletal system<br><br>- Acute Effects: May cause skin drying, itching, peeling and rashes., This material has not been tested as a whole; therefore, the information described below is based on one or more of its ingredients., May cause allergic respiratory reactions., May cause central nervous system effects., Signs and symptoms may include headache, dizziness, drowsiness, fatigue and lack of muscular coordination., May cause musculoskeletal effects., This material is not likely to be significantly absorbed via occupational routes of entry due to its chemical structure and large molecular weight., May cause muscle weakness and pain.<br><br>- Chronic Effects: No adverse effects known<br><br>- Carcinogenicity: formulation not listed by NTP, IARC or OSHA |
| GHS Classification | no classification and labelling according to GHS |

| | | |
|---|---|---|
| Additional Health Information | - | Conditions Aggravated: Hypersensitivity to this material and other materials in its chemical class. |

## 3. Composition/Information on ingredients

| | | |
|---|---|---|
| Characterization | | recombinant humanized monoclonal antibody *1 |

| **Ingredients** | **Concentration** |
|---|---|
| Omalizumab<br>CAS: 242138-07-4 | ~ 57 % |
| Sucrose<br>CAS: 57-50-1 | ~ 41 % |

*1 referring to: Omalizumab

## 4. 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<br>- in the event of symptoms get medical treatment |
| Note to physician | - | treat symptomatically |

## 5. Fire-fighting measures

| | | |
|---|---|---|
| Suitable extinguishing media | - | water spray jet, dry powder, foam, carbon dioxide, adapt extinguishing media to surrounding fire conditions |
| Flash point (liquid) | | not applicable |
| 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 |

## 6. Accidental release measures

| | | |
|---|---|---|
| Methods for cleaning up | - | collect liquids by means of sand, earth or another suitable material |

## 7. Handling and storage

**Storage**

| | | |
|---|---|---|
| Validity | - | 8 h, 2 to 8 °C *2<br>- 4 h, at room temperature *2 |

| | | |
|---|---|---|
| Packaging materials | - | vials |
| *2 referring to: | | XOLAIR reconstituted solution |

## 8. Exposure controls/Personal protection

| | | | |
|---|---|---|---|
| **Engineering Measures** | - | see 7. | |
| **Monitoring** | | | |
| 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 | - | Category 1 (Roche Group Directive K1, Annex 3): IOEL >= 100 µg/m3 | *1 |
| **Personal protective equipment** | | | |
| 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 |
| *3 referring to: | | Sucrose |

## 9. Physical and chemical properties

| | | |
|---|---|---|
| Color | | colorless, clear<br>clear to opalescent |
| Form | | clear liquid |
| Molecular mass | | ~ 149 kDa *1 |
| pH value | | 6.0 |

| | | |
|---|---|---|
| *1 referring to: | | Omalizumab |

## 10. Stability and reactivity

| | | |
|---|---|---|
| Stability | - | does not contain any antimicrobial preservative; therefore, care must be taken to ensure the sterility of the prepared solution |
| Conditions to avoid | - | light |
| | - | warming |

## 11. Toxicological information

| | | | |
|---|---|---|---|
| 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 |

*1 referring to: Omalizumab

## 12. Ecological information

| | | | |
|---|---|---|---|
| Ready biodegradability | - | globular proteins are generally well biodegradable | *1 |
| Ecotoxicity | - | monoclonal antibodies are proteins with highly specific affinity to a certain antigen; therefore, no appreciable ecotoxic potential is to be expected | *1 |

*1 referring to: Omalizumab

## 13. Disposal considerations

| | | |
|---|---|---|
| Waste from residues | - | observe local/national regulations regarding waste disposal |

## 14. Transport information

| | | |
|---|---|---|
| Note | - | not classified by transport regulations, proper shipping name non-regulated |

## 15. Regulatory information

| | | |
|---|---|---|
| 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.<br>- 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.<br>- State and local regulations vary and may impose additional reporting requirements. |

## 16. Other information

| | | |
|---|---|---|
| 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.