1. Product and Company Identification

Product name: ZENAPAX(R) (25mg/5mL) STERILE CONCENTRATE FOR INJECTION

Product code: 03 4192 4

Use: - Therapeutic Category: Immunosuppressant
- Pharmaceutical active substance (immunosuppressant)

Company information: Enquiries: Hoffmann-La Roche Inc.
340 Kingsland Street
USA-Nutley, N.J. 07110-1199
United States of America

Phone: 001-973/235 50 00
E-Mail: info.sds@roche.com

US Emergency phone: (800)-827-6243
US Chemtrec phone: (800)-424-9300

Roche Nutley Inventory Code: 25965266

2. Hazards identification

Emergency Overview

Form: liquid
Color: colorless, clear

Hazard Overview: May cause allergic reactions.

Potential Health Effects: - Exposure: Inhalation, Ingestion, Skin contact, Eye contact
- Acute Effects: May cause allergic reactions. This material has not been tested as a whole; therefore, the information described below is based on one or more of its ingredients. This material is not likely to be significantly absorbed via occupational routes of entry due to its chemical structure and large molecular weight.
- Chronic Effects: No adverse effects known
- Carcinogenicity: not listed by NTP, IARC or OSHA

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

3. Composition/Information on ingredients
## Ingredients

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Daclizumab CAS: 152923-56-3</td>
<td>20 %</td>
</tr>
</tbody>
</table>

### 4. First-aid measures

- **Eye contact**: in case of contact with eyes rinse thoroughly with plenty of water and get medical advice
- **Skin contact**: remove immediately contaminated clothes, wash affected skin with plenty of water
- **Inhalation**: in case of inhalation remove to fresh air and seek medical aid
- **Ingestion**: consult physician

### 5. Fire-fighting measures

- **Suitable extinguishing media**: water spray jet, dry powder, foam, carbon dioxide
- **Flash point (liquid)**: not applicable
- **Protection of fire-fighters**: use self-contained breathing apparatus
- **Special method of fire-fighting**: cool endangered containers with water spray

### 6. Accidental release measures

- **Personal precautions**: ensure adequate ventilation
- **Methods for cleaning up**:
  - absorb small spills with absorbent material
  - Dike large spills and pump into metal drums or absorb with absorbent material.
  - Put saturated absorbent material into a suitable labeled open head drum.
  - Secure the drum cover and move the container to a safe holding area
  - Wash spill area thoroughly with soapy water

### 7. Handling and storage

#### Handling

- Use with adequate ventilation

#### Storage

- **Storage conditions**:
  - 2 - 8 °C
  - protected from light
8. Exposure controls/Personal protection

<table>
<thead>
<tr>
<th>Engineering Measures</th>
<th>- see 7.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monitoring</td>
<td></td>
</tr>
<tr>
<td>Threshold value (Roche) air</td>
<td>Category 1 (Roche Group Directive K1, Annex 3): IOEL &gt;= 100 µg/m³</td>
</tr>
<tr>
<td>Note</td>
<td>Exposure limits: There are no exposure limits specified for this material.</td>
</tr>
<tr>
<td>Personal protective equipment</td>
<td></td>
</tr>
<tr>
<td>Respiratory protection</td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td>- respiratory protection not necessary during normal operations</td>
</tr>
<tr>
<td></td>
<td>- in case of intense formation of aerosols: particle mask</td>
</tr>
<tr>
<td>Hand protection</td>
<td>protective gloves</td>
</tr>
<tr>
<td>Eye protection</td>
<td>safety glasses</td>
</tr>
<tr>
<td>Body protection</td>
<td>protective clothing</td>
</tr>
<tr>
<td>General protective and hygiene measures</td>
<td>shower after work recommended</td>
</tr>
<tr>
<td>*1 referring to:</td>
<td>Daclizumab</td>
</tr>
</tbody>
</table>

9. Physical and chemical properties

| Color                  | colorless, clear |
| Form                   | liquid |

10. Stability and reactivity

| Stability            | stable under normal conditions |
| Conditions to avoid  | Do not shake or freeze. |
### 11. Toxicological information

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute toxicity</td>
<td>LD$_{50}$</td>
<td>&gt; 100 mg/kg (i.v., rat)</td>
</tr>
<tr>
<td></td>
<td>NOEL</td>
<td>100 mg/kg (i.v., rat)</td>
</tr>
<tr>
<td>Subchronic toxicity</td>
<td>NOEL</td>
<td>15 mg/kg/d (i.v., cynomolgus monkey; 15 d)</td>
</tr>
<tr>
<td>Mutagenicity</td>
<td></td>
<td>not mutagenic (various test systems)</td>
</tr>
</tbody>
</table>

*1 referring to: Daclizumab

### 12. Ecological information

**Note** - no ecotoxicological data available on this material

### 13. Disposal considerations

**Waste from residues**
- incinerate in qualified installation with flue gas scrubbing
- observe local/national regulations regarding waste disposal
- DO NOT FLUSH unused medications or POUR them down a sink or drain. If available in your area, use takeback programs run by household hazardous waste collection programs or community pharmacies to dispose of unused and expired medicines. If you don’t have access to a takeback program, dispose of these medicines in the household trash by removing them from their original containers and mixing them with an undesirable substance, such as used coffee grounds or kitty litter.

**Contaminated packaging**
- Empty containers must be triple rinsed prior to disposal, recycling or reuse.

**RCRA waste**
- not regulated under RCRA

### 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.
- 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.
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.