



Material Safety Data Sheet

## ZENAPAX(R) (25mg/5mL) STERILE CONCENTRATE FOR INJECTION

### 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: Local representation:  
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

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Ingredients		Concentration
Daclizumab CAS: 152923-56-3		20 %
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	<ul style="list-style-type: none"><li>- absorb small spills with absorbent material</li><li>- Dike large spills and pump into metal drums or absorb with absorbent material.</li><li>- Put saturated absorbent material into a suitable labeled open head drum.</li><li>- Secure the drum cover and move the container to a safe holding area</li><li>- Wash spill area thoroughly with soapy water</li></ul>	
7. Handling and storage		
Handling		
Technical measures	- Use with adequate ventilation	
Storage		
Storage conditions	<ul style="list-style-type: none"><li>- 2 - 8 °C</li><li>- protected from light</li></ul>	

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### 8. Exposure controls/Personal protection

**Engineering Measures** - see 7.

#### Monitoring

Threshold value (Roche) air - Category 1 (Roche Group Directive K1, Annex 3): IOEL  $\geq$  100  $\mu\text{g}/\text{m}^3$  \*1

Note - Exposure limits: There are no exposure limits specified for this material.

#### 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  
- in case of intense formation of aerosols: particle mask

Hand protection - protective gloves

Eye protection - safety glasses

Body protection - protective clothing

General protective and hygiene measures - shower after work recommended

\*1 referring to: Daclizumab

### 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.

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### 11. Toxicological information

Acute toxicity	- LD <sub>50</sub> > 100 mg/kg (i.v., rat) NOEL 100 mg/kg (i.v., rat)	*1
Subchronic toxicity	- NOEL 15 mg/kg/d (i.v., cynomolgus monkey; 15 d)	*1
Mutagenicity	- not mutagenic (various test systems)	
*1 referring to:	Daclizumab	

### 12. Ecological information

Note	- no ecotoxicological data available on this material
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### 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
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### 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.

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**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.