SECTION 1. IDENTIFICATION

Product name: OCREVUS® Vials (300 mg/10 ml)
Product code: RO496-4913/F07

Manufacturer or supplier’s details
Company name of supplier: Genentech, Inc.
Address: 1 DNA Way
South San Francisco, CA 94080
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 the OSHA Hazard Communication Standard (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

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ocrelizumab</td>
<td>637334-45-3</td>
<td>3.0</td>
</tr>
<tr>
<td>Trehalose (D+)-), 2H2O</td>
<td>6138-23-4</td>
<td>4.0</td>
</tr>
<tr>
<td>Sodium acetate trihydrate</td>
<td>6131-90-4</td>
<td>0.22</td>
</tr>
<tr>
<td>Acetic acid</td>
<td>64-19-7</td>
<td>0.02</td>
</tr>
<tr>
<td>Sorbitan, monododecanoate, poly(oxy-1,2-ethanediyl) derivs.</td>
<td>9005-64-5</td>
<td>0.02</td>
</tr>
<tr>
<td>Water</td>
<td>7732-18-5</td>
<td>&gt; 92.0</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: Carbon oxides
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: Refer to protective measures listed in sections 7 and 8.
tive equipment and emergency procedures

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: Stainless steel, glass, Vials

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>Ocrelizumab</td>
<td>637334-45-3</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: In case of contact through splashing:
SAFETY DATA SHEET

OCREVUS® Vials (300 mg/10 ml)

Material: Nitrile rubber
Break through time: > 30 min
Glove thickness: > 0.11 mm

In case of full contact:
Material: butyl-rubber
Break through time: > 480 min
Glove thickness: > 0.4 mm

Remarks: Wear appropriate protective gloves to prevent skin contact.
Replace torn or punctured gloves promptly.

Eye protection: Safety glasses
Skin and body protection: Protective suit
Hygiene measures: Handle in accordance with good industrial hygiene and safety practice.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: Aqueous solution, Clear liquid, sterile
Color: colorless
Odor: No data available
Odor Threshold: No data available
pH: 5.3
Melting point/range: No data available
Boiling point/boiling range: No data available
Evaporation rate: No data available
Self-ignition: Not applicable
Upper explosion limit / Upper flammability limit: No data available
Lower explosion limit / Lower flammability limit: No data available
Vapor pressure: No data available
Relative vapor density: No data available
Relative density: No data available
Solubility(ies)
- 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

**SECTION 10. STABILITY AND REACTIVITY**

Reactivity: No data available

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.

Incompatible materials: No data available

Hazardous decomposition products: No data available

**SECTION 11. TOXICOLOGICAL INFORMATION**

**Acute toxicity**
Not classified based on available information.

**Components:**

**Trehalose (D+)-, 2H2O:**
- Acute oral toxicity: LD50 (Rat): 16,000 mg/kg

**Ocrelizumab:**
- Acute oral toxicity: Remarks: Not bioavailable by oral administration
- Acute toxicity (other routes of administration): LD0 (cynomolgus monkey): 100 mg/kg
  Application Route: i.v. GLP: yes
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.

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:

Ocrelizumab:
Effects on fetal development
Species: cynomolgus monkey
Application Route: i.v.
Dose: 100 milligram per kilogram
Result: No teratogenic effects., No embryotoxic effects.

STOT-single exposure
Not classified based on available information.

STOT-repeated exposure
Not classified based on available information.

Aspiration toxicity
Not classified based on available information.

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Trehalose (D+)-, 2H2O:
Toxicity to fish: LC50 (Danio rerio (zebra fish)): > 100 mg/l
Exposure time: 96 h
Test Type: static test

Toxicity to fish (Chronic toxicity): NOEC (Danio rerio (zebra fish)): 100 mg/l
Exposure time: 96 d

Ecotoxicology Assessment
Acute aquatic toxicity: This product has no known ecotoxicological effects.
Chronic aquatic toxicity: This product has no known ecotoxicological effects.
Toxicity Data on Soil: Not expected to adsorb on soil.
Other organisms relevant to the environment: No data available

Ocrelizumab:
Toxicity to fish: LC50 (Poecilia reticulata (guppy)): > 100 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203
GLP: yes
Remarks: nominal concentration

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): > 100 mg/l
Exposure time: 48 h
Test Type: Immobilization
Method: OECD Test Guideline 202
GLP: yes
Remarks: nominal concentration

NOEC (Daphnia magna (Water flea)): > 100 mg/l
Exposure time: 48 h
Test Type: Immobilization
Method: OECD Test Guideline 202
GLP: yes
Remarks: nominal concentration

Toxicity to algae/aquatic plants: ErC50 (Desmodesmus subspicatus (green algae)): > 100 mg/l
Exposure time: 72 h
Test Type: Growth inhibition
Method: OECD Test Guideline 201
GLP: yes
Remarks: nominal concentration

EyC50 (Desmodesmus subspicatus (green algae)): > 100 mg/l
Exposure time: 72 h
Test Type: Growth inhibition
Method: OECD Test Guideline 201
GLP: yes
Remarks: nominal concentration
Persistence and degradability

**Components:**

**Trehalose (D+)-, 2H2O:**

- **Biodegradability:** aerobic
  - *Inoculum:* activated sludge, non-adapted
  - *Biochemical oxygen demand*
  - *Result:* Readily biodegradable.
  - *Biodegradation:* 73 %
  - *Method:* OECD Test Guideline 301A
  - *Remarks:* The 10 day time window criterion is not fulfilled.

- *aerobic*
  - *Inoculum:* activated sludge, non-adapted
  - *Dissolved organic carbon (DOC)*
  - *Result:* Readily biodegradable.
  - *Biodegradation:* 98 %
  - *Method:* OECD Test Guideline 301A

**Ocrelizumab:**

- **Biodegradability:** aerobic
  - *Theoretical oxygen demand*
  - *Result:* Readily biodegradable.
  - *Biodegradation:* 93 %
  - *Exposure time:* 28 d
  - *Method:* OECD Test Guideline 301F
  - *GLP:* yes

Bioaccumulative potential

**Components:**

**Trehalose (D+)-, 2H2O:**

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

**Ocrelizumab:**

- **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).
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 for product as supplied.
Domestic regulation
49 CFR
Not regulated as a dangerous good
Special precautions for user
Remarks: Not dangerous goods in the meaning of ADR/RID, ADN, IMDG-Code, ICAO/IATA-DGR

SECTION 15. REGULATORY INFORMATION

CERCLA Reportable Quantity
Listed substances in the product are at low enough levels to not be expected to exceed the 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
This material does not contain any components with a section 302 EHS TPQ.
SARA 311/312 Hazards: No SARA Hazards
SARA 313: This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.
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 SOCMI Intermediate or Final VOC's (40 CFR 60.489).

Clean Water Act
The following Hazardous Substances are listed under the U.S. CleanWater Act, Section 311, Table 116.4A:

Acetic acid 64-19-7 >= 0 - < 0.1 %

The following Hazardous Chemicals are listed under the U.S. CleanWater Act, Section 311, Table 117.3:

Acetic acid 64-19-7 >= 0 - < 0.1 %

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307.
This product does not contain any priority pollutants related to the U.S. Clean Water Act.

US State Regulations

Massachusetts Right To Know
No components are subject to the Massachusetts Right to Know Act.

Pennsylvania Right To Know
Water 7732-18-5
Trehalose (D+)-), 2H2O 6138-23-4
Ocrelizumab 637334-45-3
Acetic acid 64-19-7

Maine Chemicals of High Concern
Product does not contain any listed chemicals

Vermont Chemicals of High Concern
Product does not contain any listed chemicals

Washington Chemicals of High Concern
Product does not contain any listed chemicals

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

AIIC : Not in compliance with the inventory

DSL : This product contains the following components that are not on the Canadian DSL nor NDSL:

Ocrelizumab

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: Product contains substance(s) not listed on TSCA inventory.
TECI: 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 704:**

- Flammability
- Health
- Instability
- Special hazard

**HMIS® IV:**

- HEALTH / 0
- FLAMMABILITY 0
- PHYSICAL HAZARD 0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

**Full text of other abbreviations**

AIIC - Australian Inventory of Industrial Chemicals; 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
The information provided in this 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 / 2104