SAFETY DATA SHEET

OCREVUS® Vials (300 mg/10 ml)

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: DNA Way 1
94080 South San Francisco
CA
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 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>Chemical name</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>0.21</td>
</tr>
<tr>
<td>Acetic acid</td>
<td>64-19-7</td>
<td>0.025</td>
</tr>
<tr>
<td>Water</td>
<td>7732-18-5</td>
<td>92.8</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: 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 and emergency procedures: Refer to protective measures listed in sections 7 and 8.
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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>
<tr>
<td>Acetic acid</td>
<td>64-19-7</td>
<td>TWA</td>
<td>10 ppm</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL</td>
<td>15 ppm</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>10 ppm 25 mg/m³</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>ST</td>
<td>15 ppm 37 mg/m³</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>10 ppm 25 mg/m³</td>
<td>OSHA Z-1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>10 ppm 25 mg/m³</td>
<td>OSHA P0</td>
</tr>
</tbody>
</table>

Engineering measures: No data available
Personal protective equipment

Respiratory protection: No personal respiratory protective equipment normally required.

Hand protection

Material: Protective gloves

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

Flash point: does not flash

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
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:
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
Acetic acid:
Acute oral toxicity : LD50 Oral (Rat): 3,310 mg/kg

Skin corrosion/irritation
Not classified based on available information.

Components:
Acetic acid:
Species : Rabbit
Result : Causes severe burns.

Serious eye damage/eye irritation
Not classified based on available information.

Components:
Acetic acid:
Species : Rabbit
Result : Risk of serious damage to eyes.

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.

Components:
Acetic acid:
Genotoxicity in vitro : Test Type: Ames test
Method: Mutagenicity (Salmonella typhimurium - reverse mutation assay)
Result: negative
Remarks: In vitro tests did not show mutagenic effects

Method: OECD Test Guideline 473
Remarks: In vitro tests did not show mutagenic effects

Germ cell mutagenicity - Assessment : Not mutagenic in Ames Test.

Carcinogenicity
Not classified based on available information.

Components:
Acetic acid:
Remarks : No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed
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human carcinogen by IARC.

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:

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
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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

Acetic acid:
Toxicity to fish:
LC50 (Leuciscus idus (Golden orfe)): 410 mg/l
Exposure time: 48 h

NOEC (Oncorhynchus mykiss (rainbow trout)): 1,000 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

LC50 (Oncorhynchus mykiss (rainbow trout)): 160 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 203

LC100 (Oncorhynchus mykiss (rainbow trout)): 500 mg/l
Exposure time: 48 h

LC0 (Oncorhynchus mykiss (rainbow trout)): 50 mg/l
Exposure time: 48 h

LC50 (Lepomis macrochirus (Bluegill sunfish)): 75 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates:
EC50 (Daphnia magna (Water flea)): 95 mg/l
Exposure time: 24 h

EC50 (Daphnia magna (Water flea)): > 1,000 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

Persistence and degradability

Components:

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

**Acetic acid:**

Biodegradability: Zahn-Wellens Test
Concentration: 1,250 mg/l
Result: Readily biodegradable.
Biodegradation: 99%
Exposure time: 5 d
Method: OECD Test Guideline 302B

Zahn-Wellens Test
Concentration: 1,250 mg/l
Result: Readily biodegradable.
Biodegradation: 91%
Exposure time: 1 d
Method: OECD Test Guideline 302B

Result: Readily biodegradable.
Biodegradation: 71%
Exposure time: 5 d

**Bioaccumulative potential**

**Components:**

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

**Acetic acid:**
Bioaccumulation: Bioconcentration factor (BCF): 3.16
Partition coefficient: n-octanol/water: log Pow: -0.17 (77 °F / 25 °C)
pH: 7

**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

SECTION 15. REGULATORY INFORMATION

EPCRA - Emergency Planning and Community Right-to-Know

CERCLA Reportable Quantity

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Component RQ (lbs)</th>
<th>Calculated product RQ (lbs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetic acid</td>
<td>64-19-7</td>
<td>5000</td>
<td>*</td>
</tr>
</tbody>
</table>

*: Calculated RQ exceeds reasonably attainable upper limit.

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

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Component TPQ (lbs)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

SARA 311/312 Hazards: No SARA Hazards

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

US State Regulations

Massachusetts Right To Know

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

Vermont Chemicals of High Concern

Washington Chemicals of High Concern

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

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

- AICS : Not in compliance with the inventory

- 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 : Substance(s) not listed on TSCA 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:**
- Flammability: 0
- Health: 0
- Instability: 0
- 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:**
- ACGIH: USA. ACGIH Threshold Limit Values (TLV)
- NIOSH REL: USA. NIOSH Recommended Exposure Limits
- OSHA P0: USA, OSHA - TABLE Z-1 Limits for Air Contaminants - 1910.1000
- OSHA Z-1: USA, Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
- ACGIH / TWA: 8-hour, time-weighted average
- ACGIH / STEL: Short-term exposure limit
- NIOSH REL / TWA: Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
- NIOSH REL / ST: STEL - 15-minute TWA exposure that should not be exceeded at any time during a workday
- OSHA P0 / TWA: 8-hour time weighted average
- OSHA Z-1 / TWA: 8-hour time weighted average

AICS - Australian Inventory of Chemical Substances; 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 Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemi-
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<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date</th>
<th>Date of last issue: 04-18-2019</th>
<th>Date of first issue: 06-10-2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.2</td>
<td>02-17-2020</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The information provided in this Material 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.

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US / Z8 / 1810