### SECTION 1: Identification of the substance/mixture and of the company/undertaking

#### 1.1. Product identifier

<table>
<thead>
<tr>
<th>Product name</th>
<th>OCREVUS® Vials (300 mg/10 ml)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product code</td>
<td>SAP-10167394</td>
</tr>
<tr>
<td>Roche number</td>
<td>RO4964913-000</td>
</tr>
</tbody>
</table>

#### 1.2. Relevant identified uses of the substance or mixture and uses advised against

Use                                      - pharmaceutical active substance (multiple sclerosis)

#### 1.3. Details of the supplier of the safety data sheet

<table>
<thead>
<tr>
<th>Company information</th>
<th>Enquiries: Genentech, Inc. 1 DNA Way South San Francisco USA-CA 94080 United States of America</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phone</td>
<td>001-(650) 225-1000</td>
</tr>
<tr>
<td>E-Mail</td>
<td><a href="mailto:info.sds@roche.com">info.sds@roche.com</a></td>
</tr>
<tr>
<td>US Chemtrec phone</td>
<td>(800)-424-9300</td>
</tr>
</tbody>
</table>

#### 1.4. Emergency telephone number

<table>
<thead>
<tr>
<th>Emergency telephone number</th>
<th>US Chemtrec phone: (800)-424-9300</th>
</tr>
</thead>
</table>

*1 referring to: Ocrelizumab

### SECTION 2: Hazards identification

#### Classification of the substance or mixture / Label elements

| GHS Classification | no classification and labelling according to GHS |

#### Other hazards

| Note              | no information available |
SECTION 3: Composition/information on ingredients

Characterization
humanised glycosylated monoclonal anti-CD20 antibody *1

Ingredients
<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Concentration</th>
<th>GHS-Classification (pure ingredient)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trehalose dihydrate</td>
<td>3.7 %</td>
<td></td>
</tr>
<tr>
<td>Ocrelizumab</td>
<td>2.8 %</td>
<td></td>
</tr>
</tbody>
</table>

*1 referring to: Ocrelizumab

SECTION 4: First aid measures

4.1. Description of first aid measures

Eye contact
- rinse immediately with tap water for at least 20 minutes - open eyelids forcibly
- begin with medical treatment.

Skin contact
- remove immediately contaminated clothes, wash affected skin with water and soap - do not use any solvents

Inhalation
- remove the casualty to fresh air
- in the event of symptoms get medical treatment

4.2. Most important symptoms and effects, both acute and delayed

Note
- no information available

4.3. Indication of any immediate medical attention and special treatment needed

Note to physician
- treat symptomatically

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media
- water spray jet, dry powder, foam, carbon dioxide
- adapt extinguishing media to surrounding fire conditions

Flash point (liquid)
- not applicable

5.2. Special hazards arising from the substance or mixture

Specific hazards
- no particular hazards known
5.3. Advice for firefighters

Protection of fire-fighters - precipitate gases/vapours/mists with water spray
Special method of fire-fighting - remove undamaged containiners from heat radiation

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions - no special precautions required

6.2. Environmental precautions

Environmental protection - no special environmental precautions required

6.3. Methods and material for containment and cleaning up

Methods for cleaning up - collect liquids by means of sand, earth or another suitable material
- small amounts may be flushed with large amounts of water

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Technical measures - processing in closed systems, if possible superposed by inert gas (e.g. nitrogen)

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions - 2 - 8 °C
- protected from light

Packaging materials - vials

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Threshold value (Roche) air - IOEL (Internal Occupational Exposure Limit): 0.02 mg/m³

8.2. Exposure controls

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: Ocrelizumab

**SECTION 9: Physical and chemical properties**

9.1. Information on basic physical and chemical properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Color</td>
<td>colorless, clear</td>
</tr>
<tr>
<td>Form</td>
<td>aqueous solution</td>
</tr>
<tr>
<td>Molecular mass</td>
<td>~ 148 kDa *1</td>
</tr>
<tr>
<td>pH value</td>
<td>5.3</td>
</tr>
</tbody>
</table>

9.2. Other information

Note - no information available

*1 Ocrelizumab referring to:

**SECTION 10: Stability and reactivity**

10.1. Reactivity

Note - no information available

10.2. Chemical stability

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

10.3. Possibility of hazardous reactions

Note - no information available

10.4. Conditions to avoid

Conditions to avoid - warming
                        - light

10.5. Incompatible materials

Note - no information available
10.6. Hazardous decomposition products

Note - no information available

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity - LD_0 100 mg/kg (i.v., cynomolgus monkey) *1

Local effects - no information available

Sensitization - no information available

Mutagenicity - no information available

Carcinogenicity - no information available

Reproductive toxicity - not teratogenic, not embryotoxic (100 mg/kg; i.v., cynomolgus monkey) *1

STOT-single exposure - no information available

STOT-repeated exposure - no information available

Aspiration hazard - no information available

Potential Health Effects - Exposure: Inhalation, Ingestion, Skin contact, Eye contact

- Carcinogenicity: not listed by NTP, IARC or OSHA

*1 referring to: Ocrelizumab

SECTION 12: Ecological information

12.1. Toxicity

Ecotoxicity - barely toxic for algae (Desmodesmus (=Scenedesmus) subspicatus)
ErC_{50} (72 h) > 100 mg/l (nominal concentration)
EyC_{50} (72 h) > 100 mg/l (nominal concentration)
(OECD No. 201) *1

- barely toxic for fish (guppy)
LC_{50} (96 h) > 100 mg/l (nominal concentration)
(OECD No. 203) *1

- barely toxic for planktonic crustaceans (Daphnia magna)
NOEC (48 h) > 100 mg/l (nominal concentration)
EC_{50} (48 h) > 100 mg/l (nominal concentration)
(OECD No. 202) *1
12.2. Persistence and degradability

Ready biodegradability - readily biodegradable
93 %, 28 d
(Manometric Respirometry Test, OECD No. 301 F) *1

12.3. Bioaccumulative potential

Note - no information available

12.4. Mobility in soil

Note - no information available

12.5. Results of PBT and vPvB assessment

PBT/vPvB - not PBT, not vPvB *1

12.6. Other adverse effects

Note - no information available

*1 referring to: Ocrelizumab

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste from residues - observe local/national regulations regarding waste disposal
- drain very small quantities into wastewater treatment plant

SECTION 14: Transport information

Note - not classified as Dangerous Good according to the Dangerous Goods Regulations, proper shipping name non-regulated

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

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 and to local officials.
- State and local regulations vary and may impose additional reporting requirements.

SECTION 16: Other information

<table>
<thead>
<tr>
<th>Note</th>
<th>none</th>
</tr>
</thead>
<tbody>
<tr>
<td>Edition documentation</td>
<td>first edition</td>
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</table>