Safety Data Sheet

OCREVUS® Vials (300 mg/10 ml)

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

1.1. Product identifier

Product name	OCREVUS® Vials (300 mg/10 ml)	
Product code	SAP-10167394	
Roche number	RO4964913-000	*1

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

Use	-	pharmaceutical active substance (multiple sclerosis)	***1**

1.3. Details of the supplier of the safety data sheet

Company information	Enquiries: Genentech, Inc. 1 DNA Way South San Francisco USA-CA 94080 United States of America Phone 001-(650) 225-1000 E-Mail info.sds@roche.com US Chemtrec phone: (800)-424-9300	Local representation:

1.4. Emergency telephone number

Emergency telephone number	US Chemtrec phone: (800)-424-9300

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	**Concentration**	**GHS-Classification (pure ingredient)**
Ocrelizumab 637334-45-3	2.8 %	
Trehalose dihydrate 6138-23-4	3.7 %	

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 contaiiners 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	*1

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

Color	colorless, clear	
Form	aqueous solution	
Molecular mass	~ 148 kDa	*1
pH value	5.3	

9.2. Other information

Note	-	no information available

1 referring to: Ocrelizumab

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

Note	- none
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.