Safety Data Sheet

ENSPRYNG™ SC (120 mg/ml)

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

1.1. Product identifier

Product name	ENSPRYNG™ SC (120 mg/ml)	
Product code	CSE-3246	
Roche number	RO5333787-000	*1
Synonyms	- ENSPRYNG ASSD SC 120 mg/ml - Satralizumab (RO5333787) 120 mg/ml - SA237 Drug Product	

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

Use	- formulated pharmaceutical active substance

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: Satralizumab

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	monoclonal antibody	*1

Ingredients	Concentration	GHS-Classification (pure ingredient)
Satralizumab 1535963-91-7	12 %	

1 referring to: Satralizumab

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
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	- 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 - Does not present a fire hazard

5.3. Advice for firefighters

Protection of fire-fighters	- precipitate gases/vapours/mists with water spray

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

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Technical measures	-	avoid formation of aerosols

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions	-	2 - 8 °C - protected from light
Packaging materials	-	glass vials, colourless

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Threshold value (Roche) air	-	IOEL (Internal Occupational Exposure Limit): 10 µg/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 - in case of intense formation of aerosols: respirator with independent air supply or particle respectively filter mask (depending on the aerosol composition)
Hand protection	-	protective gloves (eg made of neoprene, nitrile or butyl rubber)
Eye protection	-	safety glasses

1 referring to: Satralizumab

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Color	colorless to slightly yellow	
Form	clear solution	
Molecular mass	143.415 kDa	*1
pH value	5.5 to 6.5	

9.2. Other information

Note	- no information available	

1 referring to: Satralizumab

SECTION 10: Stability and reactivity

10.1. Reactivity

Note	- no information available	

10.2. Chemical stability

Stability	- as for all other proteins, monoclonal antibodies 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 - does not contain any antimicrobial preservative; therefore, care must be taken to ensure the sterility of the prepared reconstituted solution	***1**

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

1 referring to: Satralizumab

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity	-	not bioavailable by oral administration *1
	-	NOAEL 50 mg/kg (s.c., cynomolgus monkey) *1
	-	NOAEL 200 mg/kg (i.v., cynomolgus monkey) *1
Subacute toxicity	-	NOAEL 50 mg/kg/w (s.c., cynomolgus monkey, 4 weeks) *1
Subchronic toxicity	-	NOAEL 50 mg/kg/w (s.c., cynomolgus monkey; 26 weeks) *1
Local effects	-	no information available
Sensitization		anaphylactic reactions may occur following the intravenous or subcutaneous application of proteins; rare cases of hypersensitivity have been described with other monoclonal antibodies *1
Mutagenicity	-	no information available
Carcinogenicity	-	no information available
Reproductive toxicity	-	NOAEL 50 mg/kg/week (s.c., cynomolgus monkey, 26 weeks) *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: Satralizumab

SECTION 12: Ecological information

12.1. Toxicity

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

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

12.2. Persistence and degradability

Ready biodegradability	- readily biodegradable 78 % BOD/ThOD, 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

Note	- no information available

12.6. Other adverse effects

Note	- no information available

1 referring to: Satralizumab

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste from residues	- observe local/national regulations regarding waste disposal

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

Edition documentation	- changes from previous version in sections 1, 2, 7

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.