Safety Data Sheet

FUZEON(R) Lyophilized Vials (90 mg)

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

1.1. Product identifier

Product name		FUZEON(R) Lyophilized Vials (90 mg)
Product code		SAP-10063055
Synonyms	-	FUZEON Lyophilized Vials

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

Use	-	pharmaceutical active substance (virostatic)	*1
	-	This substance is the acitve ingredient in the formulated product, FUZEON™. It inhibits fusion of HIV-1 to target cells by blocking the viral docking protein gp41.	*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: Enfuvirtide

SECTION 2: Hazards identification

Classification of the substance or mixture / Label elements

GHS Classification

Health Hazards:
3.4 Skin sensitization (Category 1)
H317 May cause an allergic skin reaction.

Signalword: Warning

Label:

Precautionary statements:
- P280 Wear protective gloves/ protective clothing / eye protection / face protection.
- P302 + P352 IF ON SKIN: Wash with plenty of soap and water.
- P312 Call a POISON CENTER or doctor/physician if you feel unwell.
- P333 + P313 If skin irritation or rash occurs: Get medical advice/attention.

Other hazards

Note - no further information available

SECTION 3: Composition/information on ingredients

Characterization: Enfuvirtide (INN) with other inactive ingredients

Ingredients	**Concentration**	**GHS-Classification (pure ingredient)**
Enfuvirtide 159519-65-0	78.3 %	- Skin sensitization (Category 1), H317

For the full text of the H-phrases mentioned in this Section, see Section 16.

SECTION 4: First aid measures

4.1. Description of first aid measures

Eye contact
- rinse immediately with tap water for 10 minutes - open eyelids forcibly

Skin contact
- remove immediately contaminated clothes, wash affected skin with water and soap - do not use any solvents
- consult a physician if skin irritation persists

Inhalation
- remove the casualty to fresh air and keep him/her calm
- 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	- formation of toxic and corrosive combustion gases (ammonia, nitrogen oxides) possible

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	- ensure adequate ventilation

6.2. Environmental precautions

Environmental protection	- do not allow to enter drains or waterways - if the substance reaches waters or the sewer system, inform the competent authority

6.3. Methods and material for containment and cleaning up

Methods for cleaning up	- collect solids (avoid dust formation) and hand over to waste removal - flush afterwards with plenty 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) - take precautionary measures against electrostatic charging
Note	- Reconstituted solution should be stored under refrigeration at 2° to 8°C (36° to 46°F) and used within 24 hours.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions	- 15 - 30 °C
Validity	- see expiry date on the label

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Threshold value (Roche) air	- IOEL (Internal Occupational Exposure Limit): 1.5 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. - in case of open handling or accidental release: particle mask or respirator with independent air supply
Hand protection	- protective gloves (eg made of neoprene, nitrile or butyl rubber)
Eye protection	- safety glasses
Analytics	- sampling on glass fibre filter and gravimetric or chemical determination

1 referring to: Enfuvirtide

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Color	white to off-white
Form	sterile, lyophilized powder

Solubility	virtually insoluble, water (pH 4.8)	*1
	~ 90 mg/l, water (pH 5.9)	*1
	~ 228'000 mg/l, water (pH 6.4)	*1
	~ 252'000 mg/l, water (pH 8.6)	*1
	< 100 mg/l, acetonitrile	*1
	~ 200 mg/l, ethanol	*1
	~ 11'900 mg/l, methanol	*1
	> 2'130'000 mg/l, dimethyl formamide	*1
pH value	8 to 9 (reconstituted solution)	*1
Melting temperature	~ 189 °C (decomposition above)	*1
	does not melt, decomposes	*1

9.2. Other information

Dissociation constant	pK_1 ~ 4.8 (calculated)	*1

1 referring to: Enfuvirtide

SECTION 10: Stability and reactivity

10.1. Reactivity

Note - no information available

10.2. Chemical stability

Stability - stable under the conditions mentioned in chapter 7

10.3. Possibility of hazardous reactions

Note - no information available

10.4. Conditions to avoid

Conditions to avoid - high temperatures (denaturation)

10.5. Incompatible materials

Materials to avoid - oxidizing agents, strong acids, strong bases (cleaving, denaturation, saponification and/or isomerization)

10.6. Hazardous decomposition products

Note - no information available

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity	- LD_{50} > 2'000 mg/kg (oral, mouse) (OECD No. 401)	*2
	- LD_0 ≥ 100 mg/kg (i.p., rat)	*1
	- LD_0 50 mg/kg (i.v., rat) LD_{50} < 100 mg/kg (i.v., rat); probably significant first pass effect in the lung associated with intravenous administration	*1
Subacute toxicity	- LD_0 10 mg/kg/d (i.v., rat, 28 d)	*1
	- NOAEL 4 mg/kg/d (i.v., Rhesus monkey, 28 d); substance administered as half dose twice daily	*1
Local effects	- skin: non-irritant (rabbit; OECD No. 404)	*2
	- eye: slightly irritating (rabbit; OECD No. 405)	*2
Sensitization	- non-sensitizing (mouse) (OECD No. 429, LLNA (Local Lymph Node Assay))	*1
	- sensitizing (guinea pig)	*1
Chronic toxicity	- NOEL 30 mg/kg/d (s.c., rat; 6 months); substance administered as half dose twice daily	*1
Mutagenicity	- not mutagenic (various in vivo and in vitro test systems)	*1
Reproductive toxicity	- no toxic reproductive effects (30 mg/kg/d; s.c., rat)	*1
Note	- not cytotoxic below 1,000 mg/l	*1
	- binds to HIV gp41 protein, blocking the docking and fusion process with the target cell	*1
	- side effect(s) during therapy: injection site inflammation, asthenia, diarrhea	***1**
	- not bioavailable by oral uptake	*1
	- elimination half-life: ~ 3 h	***1**
Potential Health Effects	- Exposure: Inhalation, Ingestion, Skin contact, Eye contact	
	- Carcinogenicity: not listed by NTP, IARC or OSHA	

1 referring to: Enfuvirtide
2 referring to: T-20 Fusion Inhibitor Crude

SECTION 12: Ecological information

12.1. Toxicity

Ecotoxicity	- barely toxic for algae (nominal concentration = 100 mg/l), algal growth enhanced in parallel with substance concentration (Selenastrum capricornutum) EC_{50} (72 h) > 100 mg/l (nominal concentration) NOErC (72 h) 100 mg/l (nominal concentration) NOEbC (72 h) 100 mg/l (nominal concentration) (OECD No. 201)	*1

- no adverse influence on substrate biodegradation (activated sludge)
  concentration (14 d) 100 mg/l
  (Manometric Respirometry Test, OECD No. 301 F) *1

12.2. Persistence and degradability

Ready biodegradability
- readily biodegradable
  100 %, 16 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
- BOD5 = 1100 mg O2/g, ThOD = 1490 mg O2/g;
  BOD5/ThOD ratio = 0.74 *1

1 referring to: Enfuvirtide

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste from residues
- observe local/national regulations regarding waste disposal
- medicines should not be disposed of via wastewater
- return to supplier or hand over to authorized disposal company
- DO NOT FLUSH unused medications or POUR them down a sink or drain. If available in your area, use takeback programs run by household hazardous waste collection programs or community pharmacies to dispose of unused and expired medicines. If you don't have access to a takeback program, dispose of these medicines in the household trash by removing them from their original containers and mixing them with an undesirable substance, such as used coffee grounds or kitty litter.

SECTION 14: Transport information

Note
- not classified by transport 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 (1-609-292-5560) and to local officials. - State and local regulations vary and may impose additional reporting requirements.

SECTION 16: Other information

Full text of H-Statements referred to under section 3

H317	May cause an allergic skin reaction.

Note	- Please note this Safety Data Sheet for the bulk product does not apply for the finished, packaged medicinal product intended for the final user.
Edition documentation	- changes from previous version in sections 2, 3, 16

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.