

**FUZEON(R) Lyophilized Vials (90 mg)**

Version 1.1                      Revision Date: 02-06-2020                      Date of last issue: 06-10-2017  
Date of first issue: 06-10-2017

**SECTION 1. IDENTIFICATION**

Product name                      : FUZEON(R) Lyophilized Vials (90 mg)  
Product code                      : 00010080811

**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  
Emergency telephone num-      : US Chemtrec phone                      (800)-424-9300  
ber

**Recommended use of the chemical and restrictions on use**

Recommended use                : Formulated pharmaceutical active substance  
Restrictions on use              : For professional users only.

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**SECTION 2. HAZARDS IDENTIFICATION****GHS classification in accordance with 29 CFR 1910.1200**

Skin sensitization                : Category 1

**GHS label elements**

Hazard pictograms                :



Signal Word                        : Warning  
Hazard Statements                : H317 May cause an allergic skin reaction.

Precautionary Statements      : **Prevention:**  
P261 Avoid breathing dust/ fume/ gas/ mist/ vapors/ spray.  
P272 Contaminated work clothing must not be allowed out of the workplace.  
P280 Wear protective gloves.  
**Response:**  
P302 + P352 IF ON SKIN: Wash with plenty of soap and water.  
P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.

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P363 Wash contaminated clothing before reuse.

**Disposal:**

P501 Dispose of contents/ container to an approved waste disposal plant.

**Other hazards**

None known.

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**SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture : Mixture

**Components**

Chemical name	CAS-No.	Concentration (% w/w)
Enfuvirtide	159519-65-0	78.3
D-Mannitol	69-65-8	19.6
Carbonic acid sodium salt (1:2)	497-19-8	2.1

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**SECTION 4. FIRST AID MEASURES**

- General advice : Move out of dangerous area.  
Show this material safety data sheet to the doctor in attendance.  
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 : Flush eyes with water as a precaution.  
Remove contact lenses.  
Protect unharmed eye.  
Keep eye wide open while rinsing.  
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.
- Most important symptoms and effects, both acute and delayed : May cause an allergic skin reaction.
- Notes to physician : The first aid procedure should be established in consultation with the doctor responsible for industrial medicine.

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**SECTION 5. FIRE-FIGHTING MEASURES**

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- Suitable extinguishing media : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
  
- Unsuitable extinguishing media : High volume water jet
  
- Specific hazards during fire fighting : No information available.
  
- Hazardous combustion products : In case of fire hazardous decomposition products may be produced such as:  
Ammonia  
Nitrogen oxides (NOx)  
Carbon oxides  
Carbon monoxide  
Carbon dioxide (CO2)  
Sodium 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 : Use personal protective equipment.  
Avoid dust formation.  
Avoid breathing dust.
  
- Environmental precautions : Prevent product from entering drains.  
Prevent further leakage or spillage if safe to do so.  
Local authorities should be advised if significant spillages cannot be contained.
  
- Methods and materials for containment and cleaning up : Keep in suitable, closed containers for disposal.

**SECTION 7. HANDLING AND STORAGE**

- Advice on protection against fire and explosion : Avoid dust formation.  
Provide appropriate exhaust ventilation at places where dust is formed.
  
- Advice on safe handling : Avoid formation of respirable particles.  
Do not breathe vapors/dust.  
Avoid exposure - obtain special instructions before use.  
Avoid contact with skin and eyes.  
For personal protection see section 8.  
Smoking, eating and drinking should be prohibited in the application area.  
Dispose of rinse water in accordance with local and national regulations.

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Persons susceptible to skin sensitization problems or asthma, allergies, chronic or recurrent respiratory disease should not be employed in any process in which this mixture is being used.

Conditions for safe storage : Keep container tightly closed in a dry and well-ventilated place.  
Electrical installations / working materials must comply with the technological safety standards.

Further information on storage conditions : See label, package insert or internal guidelines

Further information on storage stability : No decomposition if stored and applied as directed.

**SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

**Ingredients with workplace control parameters**

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Enfuvirtide	159519-65-0	IOEL	1.5 mg/m3	Roche Industrial Hygiene Committee (RIHC)

**Engineering measures** : No data available

**Personal protective equipment**

Hand protection

Material : Protective gloves

Remarks : Wear appropriate protective gloves to prevent skin contact.  
Replace torn or punctured gloves promptly.

Eye protection : Eye wash bottle with pure water  
Tightly fitting safety goggles

Skin and body protection : Choose body protection according to the amount and concentration of the dangerous substance at the work place.

Hygiene measures : When using do not eat or drink.  
When using do not smoke.  
Wash hands before breaks and at the end of workday.

**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance : lyophilized cake, sterile

# SAFETY DATA SHEET

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Color : white, off-white

Odor : Not applicable

Odor Threshold : Not applicable

pH : Not applicable

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 : No data available

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 : Not applicable

Relative density : No data available

Solubility(ies)

    Water solubility : No data available

    Solubility in other solvents : No data available

Partition coefficient: n-octanol/water : No data available

Autoignition temperature : No data available

Decomposition temperature : No data available

Viscosity

    Viscosity, dynamic : Not applicable

    Viscosity, kinematic : Not applicable

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### SECTION 10. STABILITY AND REACTIVITY

Reactivity : No dangerous reaction known under conditions of normal use.

Chemical stability : Stable under normal conditions.

Possibility of hazardous reactions : No decomposition if stored and applied as directed.

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Conditions to avoid : Direct sources of heat.

Incompatible materials : Acids  
Bases  
Oxidizing agents

Hazardous decomposition products : No data available

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**SECTION 11. TOXICOLOGICAL INFORMATION****Acute toxicity**

Not classified based on available information.

**Product:**

Acute oral toxicity : Acute toxicity estimate: 3,141 mg/kg  
Method: Calculation method

**Components:****Enfuvirtide:**

Acute oral toxicity : LD50 Oral (Mouse): > 2,000 mg/kg  
Method: OECD Test Guideline 401

**Skin corrosion/irritation**

Not classified based on available information.

**Product:**

Remarks : May cause skin irritation and/or dermatitis.

**Components:****Enfuvirtide:**

Species : Rabbit  
Method : OECD Test Guideline 404  
Result : No skin irritation  
GLP : yes

**Serious eye damage/eye irritation**

Not classified based on available information.

**Product:**

Remarks : Product dust may be irritating to eyes, skin and respiratory system.

**Components:****Enfuvirtide:**

Species : Rabbit  
Method : OECD Test Guideline 405  
GLP : yes  
Remarks : Mild eye irritation

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May cause an allergic skin reaction.

**Respiratory sensitization**

Not classified based on available information.

**Product:**

Remarks : Causes sensitization.

**Components:****Enfuvirtide:**Species : Guinea pig  
Assessment : May cause sensitization by skin contact.  
Result : Causes sensitization.Test Type : Local lymph node assay (LLNA)  
Species : Mouse  
Method : OECD Test Guideline 429  
Result : negative**Germ cell mutagenicity**

Not classified based on available information.

**Components:****Enfuvirtide:**Genotoxicity in vitro : Result: negative  
Remarks: In vitro tests did not show mutagenic effects

Genotoxicity in vivo : Result: negative

**Carcinogenicity**

Not classified based on available information.

**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:****Enfuvirtide:**Effects on fetal development : Species: Rat  
Application Route: s.c.

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Result: No adverse effects.**STOT-single exposure**

Not classified based on available information.

**STOT-repeated exposure**

Not classified based on available information.

**Repeated dose toxicity****Components:****Enfuvirtide:**Species : Rat  
NOEL : 30 mg/kg  
Application Route : s.c.  
Exposure time : 6 mSpecies : Rat  
LD0 : 10 mg/kg  
Application Route : i.v.  
Exposure time : 28 d**Aspiration toxicity**

Not classified based on available information.

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**SECTION 12. ECOLOGICAL INFORMATION****Ecotoxicity****Components:****Enfuvirtide:**Toxicity to algae/aquatic plants : EC50 (Selenastrum capricornutum (green algae)): > 100 mg/l  
Method: OECD Test Guideline 201  
Remarks: nominal concentrationNOErC (Selenastrum capricornutum (green algae)): 100 mg/l  
Method: OECD Test Guideline 201  
Remarks: nominal concentrationNOEyC (Selenastrum capricornutum (green algae)): 100 mg/l  
Method: OECD Test Guideline 201  
Remarks: nominal concentrationToxicity to microorganisms : (activated sludge): 100 mg/l  
Exposure time: 14 d  
Method: OECD Test Guideline 301F  
Remarks: no adverse influence on substrate biodegradation**Ecotoxicology Assessment**

Toxicity Data on Soil : Not expected to adsorb on soil.



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Other organisms relevant to the environment : No data available

**Persistence and degradability**

**Components:**

**Enfuvirtide:**

Biodegradability : Biodegradation: 100 %  
Exposure time: 16 d  
Method: OECD Test Guideline 301F

BOD/COD : BOD: 1100 (BOD5)COD: 1490BOD/COD: 0.74 %

**Bioaccumulative potential**

**Components:**

**Enfuvirtide:**

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

**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).

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**SECTION 13. DISPOSAL CONSIDERATIONS**

**Disposal methods**

Waste from residues : Do not contaminate ponds, waterways or ditches with chemical or used container.  
Send to a licensed waste management company.  
Can be disposed as waste water, when in compliance with local regulations.

Contaminated packaging : Empty remaining contents.  
Dispose of as unused product.  
Empty containers should be taken to an approved waste handling site for recycling or disposal.  
Do not re-use empty containers.

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**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

**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**

This material does not contain any components with a CERCLA RQ.

**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**

Components	CAS-No.	Component TPQ (lbs)
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**SARA 311/312 Hazards** : Respiratory or skin sensitization

**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 SOCM Intermediate or Final VOC's (40 CFR 60.489).

**Clean Water Act**

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.

This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

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**US State Regulations**

**Massachusetts Right To Know**

**Pennsylvania Right To Know**

Enfuvirtide	159519-65-0
D-Mannitol	69-65-8

**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.

Enfuvirtide

AICS : Not in compliance with the inventory

NZIoC : Not 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

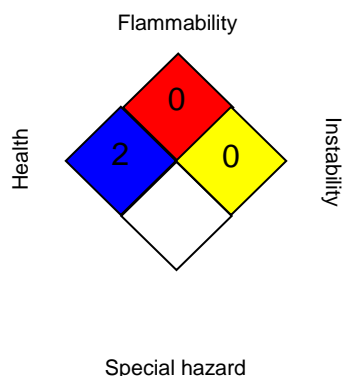
**TSCA list**

No substances are subject to a Significant New Use Rule.

No substances are subject to TSCA 12(b) export notification requirements.

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**SECTION 16. OTHER INFORMATION**

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<b>HEALTH</b>	/	2
<b>FLAMMABILITY</b>		0
<b>PHYSICAL HAZARD</b>		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**

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 Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

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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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