

Safety Data Sheet

PEGASYS(R) Vials (180 mcg/ml)

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

1.1. Product identifier

Product name PEGASYS(R) Vials (180 mcg/ml)

Product code SAP-10049980

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

Use - PEGASYS(R) is an antiviral drug used in the treatment of Hepatitis C.

1.3. Details of the supplier of the safety data sheet

Company information	Enquiries:	Local representation:
	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	

1.4. Emergency telephone number

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

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 Peginterferon α -2a with other inactive ingredients

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Ingredients	Concentration	GHS-Classification (pure ingredient)
Peginterferon α -2a 198153-51-4	~ 0.02 %	
Benzyl Alcohol 100-51-6	~ 1.0 %	- Acute toxicity (Category 4), H312 - Acute toxicity (Category 4), H332 - Acute toxicity (Category 4), H302

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
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
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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
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5.3. Advice for firefighters

Protection of fire-fighters	- precipitate gases/vapours/mists with water spray
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SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions	- no special precautions required
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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

Suitable materials - glass, tested plastics, stainless steel

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions - 2 - 8 °C
- do not freeze
- protected from light

Validity - after opening the content should be used within a short period, see "best use before" date stated on the label

Packaging materials - glass vials, colourless
- keep it in the outer carton in order to protect from light

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Threshold value (Roche) air - IOEL (Internal Occupational Exposure Limit): 0.06 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

Hand protection - protective gloves (eg made of neoprene, nitrile or butyl rubber)

Eye protection - safety glasses

*1 referring to: Peginterferon α-2a

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Color	colorless, clear
Form	sterile liquid
Density	1.004 g/ml
pH value	5.5 to 6.5

9.2. Other information

Note	- no information available
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SECTION 10: Stability and reactivity

10.1. Reactivity

Note	- no information available
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10.2. Chemical stability

Stability	- stable under normal conditions
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10.3. Possibility of hazardous reactions

Note	- no information available
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10.4. Conditions to avoid

Conditions to avoid	- light
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10.5. Incompatible materials

Note	- no information available
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10.6. Hazardous decomposition products

Note	- no information available
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SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity	- NOEL	300	µg/kg	(i.v., cynomolgus monkey)	*1
	- NOEL	6'750	µg/kg	(s.c., cynomolgus monkey)	*1

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Subacute toxicity	- NOEL ~ 600 µg/kg/d (i.v., several species, 28 d)	*1
Sensitization	- approx. one fourth of patients develop antibodies against pure Interferon α -2A; however, these cause no clinical symptoms	*1
Mutagenicity	- not mutagenic (various in vitro test systems)	*1
Potential Health Effects	- Exposure: Inhalation, Ingestion, Skin contact, Eye contact - Carcinogenicity: not listed by NTP, IARC or OSHA	
*1 referring to:	Peginterferon α -2a	

SECTION 12: Ecological information

12.1. Toxicity

Ecotoxicity	- barely toxic for fish (carp) LC ₅₀ (96 h) > 300 mg/l NOEC (96 h) 300 mg/l (OECD No. 203, semistatic)	*1
	- barely toxic for planktonic crustaceans (Daphnia magna) LC ₅₀ (48 h) > 300 mg/l NOEC (48 h) 300 mg/l (OECD No. 202, semistatic)	*1
	- barely inhibitory on aerobic bacterial respiration (activated sludge) concentration (28 d) 3.3 mg/l (Closed Bottle Test, OECD No. 301 D)	*1

12.2. Persistence and degradability

Ready biodegradability	- not readily biodegradable ≤ 22 %, 28 d (Closed Bottle Test, OECD No. 301 D)	*1
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12.3. Bioaccumulative potential

Note	- no information available	
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12.4. Mobility in soil

Note	- no information available	
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12.5. Results of PBT and vPvB assessment

Note	- no information available	
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12.6. Other adverse effects

Note	- no information available	
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*1 referring to:	Peginterferon α -2a	
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SECTION 13: Disposal considerations

13.1. Waste treatment methods

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| Waste from residues | <ul style="list-style-type: none">- 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 |
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SECTION 14: Transport information

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| Note | <ul style="list-style-type: none">- not classified by transport regulations, proper shipping name non-regulated |
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SECTION 15: Regulatory information

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

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| TSCA Status | <ul style="list-style-type: none">- FDA Exemption - not on inventory |
| Reporting Requirements | <ul style="list-style-type: none">- 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

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| H302 | Harmful if swallowed. |
| H312 | Harmful in contact with skin. |
| H332 | Harmful if inhaled. |

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| Edition documentation | <ul style="list-style-type: none">- changes from previous version in sections 2, 3, 16 |
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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.