

Safety Data Sheet

PEGASYS(R) Prefilled Syringe (180 mcg/0.5 ml)

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

1.1. Product identifier

Product name PEGASYS(R) Prefilled Syringe (180 mcg/0.5 ml)
 Product code SAP-10049982
 Synonyms - PEGASYS PFS (180 mcg/0.5 ml)

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: 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:
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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	< 0.1 %	
Benzyl Alcohol 100-51-6	~ 1 %	- Acute toxicity (Category 4), H312 - Acute toxicity (Category 4), H332 - Acute toxicity (Category 4), H302
<i>For the full text of the 'Hazard statements' mentioned in this Section, see Section 16.</i>		
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 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	
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	
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	

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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 - prefilled syringes
- 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

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SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Color	colorless to slightly yellow
Form	sterile liquid
Density	1.004 g/ml
pH value	5.8 to 6.2

9.2. Other information

Note - no information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Note - no information available

10.2. Chemical stability

Stability - stable under normal conditions

10.3. Possibility of hazardous reactions

Note - no information available

10.4. Conditions to avoid

Conditions to avoid - 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	- 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
Local effects	- no information available	
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
Carcinogenicity	- no information available	
Reproductive toxicity	- no information available	
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:	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
	- barely toxic for fish (rainbow trout) LC ₅₀ (96 h) 315 mg/l (OECD No. 203)	*2
	- moderately toxic for fish (bluegill sunfish) LC ₅₀ (96 h) 10 mg/l (OECD No. 203)	*2
	- barely toxic for algae (Scenedesmus (=Desmodesmus) subspicatus) EC ₀ (96 h) 640 mg/l (method not known)	*2
	- barely toxic for planktonic crustaceans (Daphnia magna) EC ₀ (48 h) 369 mg/l (method not known)	*2

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- barely toxic for fish (fathead minnow)
LC₅₀ (96 h) 460 mg/l
(method not known) *2
- barely toxic for microorganisms (*Pseudomonas putida*)
EC₁₀ (48 h) 658 mg/l
(method not known) *2
- barely toxic for algae (*Scenedesmus quadricauda*)
IC₅ (96 h) 640 mg/l *2
- barely toxic for protozoa (*Tetrahymena pyriformis*)
EC₅₀ (48 h) 854 mg/l *2

12.2. Persistence and degradability

- Ready biodegradability
- not readily biodegradable
≤ 22 %, 28 d
(Closed Bottle Test, OECD No. 301 D) *1
 - readily biodegradable
> 92 %, 28 d *2
- Inherent biodegradability
- well inherently biodegradable
100 %, 2 days
(Zahn-Wellens test, OECD No. 302 B) *2

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: Peginterferon α -2a

*2 referring to: Benzyl Alcohol

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

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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

Full text of H-Statements referred to under section 3

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

Edition documentation - changes from previous version in sections 2

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.