Safety Data Sheet

PEGASYS ProClick™ Autoinjector (180 mcg/0.5 ml)

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

1.1. Product identifier

Product name		PEGASYS ProClick™ Autoinjector (180 mcg/0.5 ml)
Product code		SAP-10143819
Synonyms	-	PEGASYS Autoinjector 180 mcg

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:

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 used in an auto-injector	
Ingredients	**Concentration**	**GHS-Classification (pure ingredient)**
Peginterferon α-2a 198153-51-4	< 0.1 %	
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 'Hazard statements' 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 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

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	-	autoinjector - 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 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

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

12.2. Persistence and degradability

Ready biodegradability	- not readily biodegradable ≤ 22 %, 28 d (Closed Bottle Test, OECD No. 301 D)	*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: Peginterferon α-2a

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

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 3, 15

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.