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

Local representation:
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
PEGASYS ProClick™ Autoinjector (180 mcg/0.5 ml)

SECTION 3: Composition/information on ingredients

Characterization  
Peginterferon α-2a with other inactive ingredients used in an auto-injector

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>Concentration</th>
<th>GHS-Classification (pure ingredient)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peginterferon α-2a</td>
<td>&lt; 0.1 %</td>
<td>- Acute toxicity (Category 4), H312</td>
</tr>
<tr>
<td>198153-51-4</td>
<td></td>
<td>- Acute toxicity (Category 4), H332</td>
</tr>
<tr>
<td>Benzyl Alcohol</td>
<td>1.0 %</td>
<td>- Acute toxicity (Category 4), H302</td>
</tr>
<tr>
<td>100-51-6</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

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

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

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)
  LC₅₀ (96 h) > 300 mg/l
  NOEC (96 h) 300 mg/l
  (OECD No. 203, semistatic) *1
- barely toxic for planktonic crustaceans (Daphnia magna)
  LC₅₀ (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 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 |
| H302 Harmful if swallowed. |
| H312 Harmful in contact with skin. |
| H332 Harmful if inhaled. |

| 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.