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

1.1. Product identifier

<table>
<thead>
<tr>
<th>Product name</th>
<th>PEGASYS ProClick™ Autoinjector (135 mcg/0.5 ml)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product code</td>
<td>SAP-10144640</td>
</tr>
<tr>
<td>Synonyms</td>
<td>PEGASYS Autoinjector 135 mcg</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Company information</th>
<th>Enquiries: Genentech, Inc. 1 DNA Way South San Francisco USA-CA 94080 United States of America</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Phone 001-(650) 225-1000 E-Mail <a href="mailto:info.sds@roche.com">info.sds@roche.com</a> US Chemtrec phone: (800)-424-9300</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Characterization</th>
<th>Peginterferon α-2a with other inactive ingredients used in an auto-injector</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ingredients</td>
<td>Concentration</td>
</tr>
<tr>
<td>Peginterferon α-2a</td>
<td>&lt; 0.1 %</td>
</tr>
<tr>
<td>198153-51-4</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>Benzyl Alcohol</td>
<td>1.0 %</td>
</tr>
<tr>
<td>100-51-6</td>
<td></td>
</tr>
<tr>
<td>01-2119492630-38</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
PEGASYS ProClick™ Autoinjector (135 mcg/0.5 ml)

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)
  $\text{LC}_{50}$ (96 h) $> 300$ mg/l
  NOEC (96 h) 300 mg/l
  (OECD No. 203, semistatic) *1
- barely toxic for planktonic crustaceans (Daphnia magna)
  $\text{LC}_{50}$ (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
  $\leq 22\%$, 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.