**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

<table>
<thead>
<tr>
<th>Company information</th>
<th>Enquiries: Genentech, Inc.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1 DNA Way</td>
</tr>
<tr>
<td></td>
<td>South San Francisco</td>
</tr>
<tr>
<td></td>
<td>USA-CA 94080</td>
</tr>
<tr>
<td></td>
<td>United States of America</td>
</tr>
</tbody>
</table>

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

<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></td>
<td></td>
<td>- Acute toxicity (Category 4), H302</td>
</tr>
<tr>
<td>Benzyl Alcohol</td>
<td>~ 1 %</td>
<td></td>
</tr>
<tr>
<td>100-51-6</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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 - 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

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

<table>
<thead>
<tr>
<th>Property</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Color</td>
<td>colorless to slightly yellow</td>
</tr>
<tr>
<td>Form</td>
<td>sterile liquid</td>
</tr>
<tr>
<td>Density</td>
<td>1.004 g/ml</td>
</tr>
<tr>
<td>pH value</td>
<td>5.8 to 6.2</td>
</tr>
</tbody>
</table>

#### 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

<table>
<thead>
<tr>
<th>Type</th>
<th>NOEL</th>
<th>µg/kg</th>
<th>Route</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute toxicity</td>
<td>300</td>
<td>(i.v., cynomolgus monkey)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>6'750</td>
<td>(s.c., cynomolgus monkey)</td>
<td></td>
</tr>
</tbody>
</table>

*1
### Subacute toxicity
- NOEL ~ 600 µg/kg/d (i.v., several species, 28 d)

### Local effects
- no information available

### Sensitization
approx. one fourth of patients develop antibodies against pure Interferon α-2A; however, these cause no clinical symptoms

### Mutagenicity
- not mutagenic (various in vitro test systems)

### 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)
  \[ LC_{50} (96 \text{ h}) > 300 \text{ mg/l} \]
  NOEC (96 h) 300 mg/l
  (OECD No. 203, semistatic)

- barely toxic for planktonic crustaceans (Daphnia magna)
  \[ LC_{50} (48 \text{ h}) > 300 \text{ mg/l} \]
  NOEC (48 h) 300 mg/l
  (OECD No. 202, semistatic)

- barely inhibitory on aerobic bacterial respiration (activated sludge) concentration (28 d) 3.3 mg/l
  (Closed Bottle Test, OECD No. 301 D)

- barely toxic for fish (rainbow trout)
  \[ LC_{50} (96 \text{ h}) > 315 \text{ mg/l} \]
  (OECD No. 203)

- moderately toxic for fish (bluegill sunfish)
  \[ LC_{50} (96 \text{ h}) 10 \text{ mg/l} \]
  (OECD No. 203)

- barely toxic for algae (Scenedesmus (=Desmodesmus) subspicatus)
  \[ EC_{0} (96 \text{ h}) > 640 \text{ mg/l} \]
  (method not known)

- barely toxic for planktonic crustaceans (Daphnia magna)
  \[ EC_{0} (48 \text{ h}) > 369 \text{ mg/l} \]
  (method not known)
- barely toxic for fish (fathead minnow)
  \( \text{LC}_{50} \) (96 h) 460 mg/l
  (method not known) \(^2\)
- barely toxic for microorganisms (Pseudomonas putida)
  \( \text{EC}_{10} \) (48 h) 658 mg/l
  (method not known) \(^2\)
- barely toxic for algae (Scenedesmus quadricauda)
  \( \text{IC}_{5} \) (96 h) 640 mg/l
  (method not known) \(^2\)
- barely toxic for protozoa (Tetrahymena pyriformis)
  \( \text{EC}_{50} \) (48 h) 854 mg/l
  (method not known) \(^2\)

### 12.2. Persistence and degradability

<table>
<thead>
<tr>
<th>Ready biodegradability</th>
<th>- not readily biodegradable</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>( \leq 22 % ), 28 d (^1)</td>
</tr>
<tr>
<td></td>
<td>(Closed Bottle Test, OECD No. 301 D)</td>
</tr>
<tr>
<td></td>
<td>- readily biodegradable</td>
</tr>
<tr>
<td></td>
<td>&gt; 92 %, 28 d (^2)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Inherent biodegradability</th>
<th>- well inherently biodegradable</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>100 %, 2 days (^2)</td>
</tr>
<tr>
<td></td>
<td>(Zahn-Wellens test, OECD No. 302 B)</td>
</tr>
</tbody>
</table>

### 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 \( \alpha \)-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

---

19.1.17

Date: 31.10.17/LS (SEISMO)  
Replacing edition of: 19.1.17  
Page: 6/7
## 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.