# Safety Data Sheet

**PEGASYS(R) Vials (180 mcg/ml)**

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

### 1.1. Product identifier

- **Product name**: PEGASYS(R) Vials (180 mcg/ml)
- **Product code**: SAP-10049980

### 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.
  - **Address**: 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**: (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) Vials (180 mcg/ml)

### Ingredients

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Concentration</th>
<th>GHS-Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peginterferon α-2a</td>
<td>~ 0.02 %</td>
<td>- Acute toxicity (Category 4), H312</td>
</tr>
<tr>
<td></td>
<td>198153-51-4</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>~ 1.0 %</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 - glass vials, colourless
- 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>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Color</td>
<td>colorless, clear</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>5.5 to 6.5</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

#### Acute toxicity

<table>
<thead>
<tr>
<th>Type</th>
<th>NOEL</th>
<th>Value</th>
<th>(Route)</th>
<th>Species</th>
<th>*1</th>
</tr>
</thead>
<tbody>
<tr>
<td>(i.v., cynomolgus monkey)</td>
<td>300 µg/kg</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(s.c., cynomolgus monkey)</td>
<td>6'750 µg/kg</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
PEGASYS(R) Vials (180 mcg/ml)

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
  $\leq 22 \%$, 28 d
  (Closed Bottle Test, OECD No. 301 D) *1

12.3. Bioaccumulative potential

Note
- no information available
PEGASYS(R) Vials (180 mcg/ml)

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
- return to supplier or hand over to authorized disposal company

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.