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

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

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</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peginterferon α-2a</td>
<td>&lt; 0.1 %</td>
<td></td>
</tr>
<tr>
<td>198153-51-4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Benzyl Alcohol</td>
<td>~ 1 %</td>
<td>- Acute toxicity (Category 4), H312</td>
</tr>
<tr>
<td>100-51-6</td>
<td></td>
<td>- Acute toxicity (Category 4), H332</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Acute toxicity (Category 4), H302</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 - 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>Value</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 (i.v., cynomolgus monkey)</th>
<th>NOEL</th>
<th>µg/kg (s.c., cynomolgus monkey)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute toxicity</td>
<td>300</td>
<td>6'750</td>
<td>6'750</td>
<td>300</td>
</tr>
</tbody>
</table>

Date: 9.7.15/LS (SEISMO)  Replacing edition of: 22.3.14  Page: 4/7
### 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

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### SECTION 12: Ecological information

#### 12.1. Toxicity

<table>
<thead>
<tr>
<th>Ecotoxicity</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>- barely toxic for fish (carp)</td>
<td></td>
</tr>
<tr>
<td>LC50 (96 h) &gt; 300 mg/l</td>
<td></td>
</tr>
<tr>
<td>NOEC (96 h) 300 mg/l</td>
<td></td>
</tr>
<tr>
<td>(OECD No. 203, semistatic)</td>
<td>*1</td>
</tr>
<tr>
<td>- barely toxic for planktonic crustaceans (Daphnia magna)</td>
<td></td>
</tr>
<tr>
<td>LC50 (48 h) &gt; 300 mg/l</td>
<td></td>
</tr>
<tr>
<td>NOEC (48 h) 300 mg/l</td>
<td></td>
</tr>
<tr>
<td>(OECD No. 202; semistatic)</td>
<td>*1</td>
</tr>
<tr>
<td>- barely inhibitory on aerobic bacterial respiration (activated sludge) concentration (28 d) 3.3 mg/l</td>
<td></td>
</tr>
<tr>
<td>(Closed Bottle Test, OECD No. 301 D)</td>
<td>*1</td>
</tr>
<tr>
<td>- barely toxic for fish (rainbow trout)</td>
<td></td>
</tr>
<tr>
<td>LC50 (96 h) 315 mg/l</td>
<td></td>
</tr>
<tr>
<td>(OECD No. 203)</td>
<td>*2</td>
</tr>
<tr>
<td>- moderately toxic for fish (bluegill sunfish)</td>
<td></td>
</tr>
<tr>
<td>LC50 (96 h) 10 mg/l</td>
<td></td>
</tr>
<tr>
<td>(OECD No. 203)</td>
<td>*2</td>
</tr>
<tr>
<td>- barely toxic for algae (Scenedesmus (=Desmodesmus) subspicatus)</td>
<td></td>
</tr>
<tr>
<td>EC0 (96 h) 640 mg/l</td>
<td></td>
</tr>
<tr>
<td>(method not known)</td>
<td>*2</td>
</tr>
<tr>
<td>- barely toxic for planktonic crustaceans (Daphnia magna)</td>
<td></td>
</tr>
<tr>
<td>EC0 (48 h) 369 mg/l</td>
<td></td>
</tr>
<tr>
<td>(method not known)</td>
<td>*2</td>
</tr>
<tr>
<td>- barely toxic for fish (fathead minnow)</td>
<td></td>
</tr>
<tr>
<td>LC50 (96 h) 460 mg/l</td>
<td></td>
</tr>
<tr>
<td>(method not known)</td>
<td>*2</td>
</tr>
<tr>
<td>- barely toxic for microorganisms (Pseudomonas putida)</td>
<td></td>
</tr>
<tr>
<td>EC10 (48 h) 658 mg/l</td>
<td></td>
</tr>
<tr>
<td>(method not known)</td>
<td>*2</td>
</tr>
<tr>
<td>- barely toxic for algae (Scenedesmus quadricauda)</td>
<td></td>
</tr>
<tr>
<td>IC5 (96 h) 640 mg/l</td>
<td></td>
</tr>
<tr>
<td>*2</td>
<td></td>
</tr>
<tr>
<td>- barely toxic for protozoa (Tetrahymena pyriformis)</td>
<td></td>
</tr>
<tr>
<td>EC50 (48 h) 854 mg/l</td>
<td></td>
</tr>
<tr>
<td>*2</td>
<td></td>
</tr>
</tbody>
</table>
12.2. Persistence and degradability

Ready biodegradability  

- not readily biodegradable  
  \[ \leq 22\%, \text{28 d} \]  
  (Closed Bottle Test, OECD No. 301 D) \( ^1 \)  
- readily biodegradable  
  \[ > 92\%, \text{28 d} \]  

Inherent biodegradability  

- well inherently biodegradable  
  \[ 100\%, \text{2 days} \]  
  (Zahn-Wellens test, OECD No. 302 B) \( ^2 \)

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

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

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.