Material Safety Data Sheet

PEGASYS(R) Prefilled Syringes (0.135 mg/0.5 ml)

1. Product and Company Identification

Product name	PEGASYS(R) Prefilled Syringes (0.135 mg/0.5 ml)
Product code	03 4208 4
Company information	Enquiries: Local representation: Hoffmann-La Roche Inc. 340 Kingsland Street USA-Nutley, N.J. 07110-1199 United States of America Phone 001-973/235 50 00 US Emergency phone: (800)-827-6243 US Chemtrec phone: (800)-424-9300
Characterization	final product

2. Composition/Information on ingredients

Ingredients	Concentration
Water CAS: 7732-18-5	~ 98 %
Peginterferon α-2a CAS: 198153-51-4	< 0.1 %
Benzyl alcohol protein grade CAS: 100-51-6	~ 1 %
Sodium chloride CAS: 7647-14-5	~ 0.8 %

3. Hazards identification

Emergency Overview

Form	liquid
Color	colorless
Hazard Overview	- May cause allergic reactions.

Potential Health Effects	- Exposure: Inhalation, Ingestion, Skin contact, Eye contact, Injection - Target Organs: skin, eyes, mucous membranes, Central nervous system, Hematopoietic/blood system, Immune System - Acute Effects: May cause eye irritation., May cause skin irritation., May cause allergic reactions., This material has not been tested as a whole; therefore, the information described below is based on one or more of its ingredients., May cause mucous membrane irritation (inflammation)., May cause central nervous system effects., Signs and symptoms may include headache, dizziness, drowsiness, fatigue and lack of muscular coordination., May cause "flu-like" symptoms such as fever, fatigue, chills, headache, nausea and muscular pain., This material is not likely to be significantly absorbed via occupational routes of entry due to its chemical structure and large molecular weight. - Chronic Effects: May cause blood system changes. - Carcinogenicity: formulation not listed by NTP, IARC or OSHA

4. First-aid measures

Eye contact	- in case of contact with eyes rinse thoroughly with plenty of water and get medical advice
Skin contact	- remove immediately contaminated clothes, wash affected skin with plenty of water
Inhalation	- in case of inhalation remove to fresh air and seek medical aid
Ingestion	- consult physician

5. Fire-fighting measures

Suitable extinguishing media	- water spray jet, dry powder, foam, carbon dioxide
Flash point (liquid)	Not established
Protection of fire-fighters	- use self-contained breathing apparatus
Special method of fire-fighting	- cool endangered containers with water spray

6. Accidental release measures

Personal precautions	- ensure adequate ventilation
Methods for cleaning up	- absorb small spills with absorbent material - Dike large spills and pump into metal drums or absorb with absorbent material. - Put saturated absorbent material into a suitable labeled open head drum. - Secure the drum cover and move the container to a safe holding area - Mop or flush the area with water - Check area for residual material and repeat clean up if detected

7. Handling and storage

Handling

Technical measures	- Use with adequate ventilation

Storage

Storage conditions	- 2 - 8 °C - do not freeze - protected from light

8. Exposure controls/Personal protection

Engineering Measures	- see 7.	
Threshold value (Roche) air	- IOEL: 0.06 μg/m^3	*1

Personal protective equipment

Respiratory protection	- Respiratory protection is recommended as a precaution to minimze 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
Eye protection	- safety glasses
Body protection	- protective clothing

*1 referring to: Peginterferon α-2a

9. Physical and chemical properties

Color	colorless
Form	liquid
pH value	5.5 to 6.5

10. Stability and reactivity

Stability	- stable under normal conditions
Conditions to avoid	- light
Materials to avoid	- None known

11. Toxicological information

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

*1 referring to: Peginterferon α-2a

12. Ecological information

Ready biodegradability	- not readily biodegradable ≤ 22 %, 28 d (Closed Bottle Test, OECD No. 301 D) *1
Ecotoxicity	- moderately toxic for fish (bluegill sunfish) LC_{50} (96 hours) 10 mg/l *2 - barely toxic for planktonic crustaceans (Daphnia magna) EC_{100} (24 hours) 100 mg/l *2 - moderately toxic for algae (green algae) EC_{50} 10 mg/l *2 - 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

Note	-	standard Pegasys solution at a concentration of 0.14% PEG-IFN was used for ecotoxicity tests; the results refer to pure PEG-IFN *1

*1 referring to: Peginterferon α-2a
*2 referring to: Benzyl alcohol protein grade

13. Disposal considerations

Waste from residues	-	incinerate in qualified installation with flue gas scrubbing
	-	observe local/national regulations regarding waste disposal
RCRA waste	-	not regulated under RCRA

14. Transport information

Note	-	not classified by transport regulations, proper shipping name non-regulated

15. Regulatory information

TSCA Status	-	FDA Exemption - not on inventory
	-	On TSCA inventory*3
	-	On TSCA inventory*2
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.

*2 referring to: Benzyl alcohol protein grade
*3 referring to: Sodium chloride

16. Other information

Use	-	PEGASYS(R) is an antiviral drug used in the treatment of Hepatitis C.
Edition documentation	-	first edition

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.