

**1. Product and Company Identification**

Product name	PEGASYS(R) Vials (0.18 mg/ml)	
Product code	03 4357 9	
Use	- PEGASYS(R) is an antiviral drug used in the treatment of Hepatitis C.	
Company information	Enquiries: Hoffmann-La Roche Inc. 340 Kingsland Street USA-Nutley, N.J. 07110-1199 United States of America	Local representation:
	Phone 001-973/235 50 00 E-Mail info.sds@roche.com	
	US Emergency phone: (800)-827-6243 US Chemtrec phone: (800)-424-9300	

2. Hazards identification**Emergency Overview**

Form	liquid
Color	colorless
Hazard Overview	- May cause allergic reactions.
Potential Health Effects	<ul style="list-style-type: none">- Exposure: Inhalation, Ingestion, Skin contact, Eye contact- 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

PEGASYS(R) Vials (0.18 mg/ml)

3. Composition/Information on ingredients

Characterization	final product
Ingredients	Concentration
Water CAS: 7732-18-5	~ 98 %
Peginterferon α -2a CAS: 198153-51-4	~ 0.02 %
Benzyl alcohol protein grade CAS: 100-51-6	~ 1 %
Sodium chloride CAS: 7647-14-5	~ 0.8 %

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	<ul style="list-style-type: none">- 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

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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 (Internal Occupational Exposure Limit): 0.06 µg/m³ *1

Personal protective equipment

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

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

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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 referring to: Peginterferon α -2a

*2 referring to: Benzyl alcohol protein grade

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13. Disposal considerations

- Waste from residues
- incinerate in qualified installation with flue gas scrubbing
 - observe local/national regulations regarding waste disposal
 - DO NOT FLUSH unused medications or POUR them down a sink or drain. If available in your area, use takeback programs run by household hazardous waste collection programs or community pharmacies to dispose of unused and expired medicines. If you don't have access to a takeback program, dispose of these medicines in the household trash by removing them from their original containers and mixing them with an undesirable substance, such as used coffee grounds or kitty litter.
- 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
- 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.
- *3 referring to: Sodium chloride

16. Other information

- Edition documentation
- changes from previous version in sections 13

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.