

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

Version 0.0 Revision Date: 10-21-2020 Date of last issue: 06-10-2017
Date of first issue: 12-05-2015

SECTION 1. IDENTIFICATION

Product name : PEGASYS(R) Prefilled Syringe (180 mcg/0.5 ml)
Product code : 00010049982

Manufacturer or supplier's details

Company name of supplier : Genentech, Inc.
Address : DNA Way 1
 94080 South San Francisco
 CA
 USA
Telephone : 001-(650) 225-1000
E-mail address : info.sds@roche.com
Emergency telephone
Emergency telephone num- : US Chemtrec phone (800)-424-9300
ber

Recommended use of the chemical and restrictions on use

Recommended use : Formulated pharmaceutical active substance
Restrictions on use : For professional users only.

SECTION 2. HAZARDS IDENTIFICATION**GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)**

Not a hazardous substance or mixture.

GHS label elements

Not a hazardous substance or mixture.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
PEG-Interferon-alpha2A	198153-51-4	0.036
Benzenemethanol	100-51-6	1.0
Sodium chloride (NaCl)	7647-14-5	0.8
Sodium acetate trihydrate	6131-90-4	< 0.3
Sorbitan, mono-(9Z)-9-octadecenoate, poly(oxy-1,2-ethanediyl) derivs.	9005-65-6	< 0.01
Water	7732-18-5	> 97.0

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

Version
0.0

Revision Date:
10-21-2020

Date of last issue: 06-10-2017
Date of first issue: 12-05-2015

SECTION 4. FIRST AID MEASURES

- General advice : Do not leave the victim unattended.

- If inhaled : Move to fresh air.
If unconscious, place in recovery position and seek medical advice.
If symptoms persist, call a physician.

- In case of skin contact : If on skin, rinse well with water.

- In case of eye contact : Immediately flush eye(s) with plenty of water.
Remove contact lenses.
Protect unharmed eye.
If eye irritation persists, consult a specialist.

- If swallowed : Keep respiratory tract clear.
Do not give milk or alcoholic beverages.
Never give anything by mouth to an unconscious person.
If symptoms persist, call a physician.
Rinse mouth with water.

- Most important symptoms and effects, both acute and delayed : None known.

- Notes to physician : The first aid procedure should be established in consultation with the doctor responsible for industrial medicine.

SECTION 5. FIRE-FIGHTING MEASURES

- Suitable extinguishing media : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

- Specific hazards during fire fighting : No information available.

- Hazardous combustion products : Carbon oxides

- Further information : Standard procedure for chemical fires.
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

- Special protective equipment for fire-fighters : Wear self-contained breathing apparatus for firefighting if necessary.

SECTION 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : Refer to protective measures listed in sections 7 and 8.

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

Version
0.0

Revision Date:
10-21-2020

Date of last issue: 06-10-2017
Date of first issue: 12-05-2015

- Environmental precautions : Local authorities should be advised if significant spillages cannot be contained.
- Methods and materials for containment and cleaning up : Wipe up with absorbent material (e.g. cloth, fleece).
Keep in suitable, closed containers for disposal.

SECTION 7. HANDLING AND STORAGE

- Advice on protection against fire and explosion : Normal measures for preventive fire protection.
- Advice on safe handling : For personal protection see section 8.
Smoking, eating and drinking should be prohibited in the application area.
- Conditions for safe storage : Electrical installations / working materials must comply with the technological safety standards.
- Further information on storage conditions : See label, package insert or internal guidelines
- Materials to avoid : No materials to be especially mentioned.
- Storage temperature : Protected from heat and light
- Further information on storage stability : No decomposition if stored and applied as directed.
- Packaging material : Suitable material: Stainless steel, glass, Prefilled syringes, Autoinjector

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Benzenemethanol	100-51-6	TWA	10 ppm	US WEEL
PEG-Interferon-alpha2A	198153-51-4	IOEL	0.00006 mg/m3	Roche Industrial Hygiene Committee (RIHC)

Engineering measures : No data available

Personal protective equipment

Respiratory protection : No personal respiratory protective equipment normally required.

Hand protection

PEGASYS(R) Prefilled Syringe (180 mcg/0.5 ml)Version
0.0Revision Date:
10-21-2020Date of last issue: 06-10-2017
Date of first issue: 12-05-2015

Material : Protective gloves

Remarks : Wear appropriate protective gloves to prevent skin contact.
Replace torn or punctured gloves promptly.

Eye protection : Safety glasses

Skin and body protection : Protective suit

Hygiene measures : Handle in accordance with good industrial hygiene and safety practice.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : Aqueous solution, sterile

Color : colorless, light yellow

Odor : No data available

Odor Threshold : No data available

pH : 5.8 - 6.2

Melting point/range : No data available

Boiling point/boiling range : No data available

Flash point : does not flash

Evaporation rate : No data available

Self-ignition : No data available

Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

Vapor pressure : No data available

Relative vapor density : No data available

Relative density : No data available

Density : 1.004 g/cm³

Solubility(ies)

Water solubility : completely miscible

Solubility in other solvents : No data available

Partition coefficient: n- : No data available

PEGASYS(R) Prefilled Syringe (180 mcg/0.5 ml)Version
0.0Revision Date:
10-21-2020Date of last issue: 06-10-2017
Date of first issue: 12-05-2015

octanol/water

Autoignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, dynamic : No data available

Viscosity, kinematic : No data available

Oxidizing properties : The substance or mixture is not classified as oxidizing.

SECTION 10. STABILITY AND REACTIVITY

Reactivity : No dangerous reaction known under conditions of normal use.

Chemical stability : Stable under normal conditions.

Possibility of hazardous reactions : Stable under recommended storage conditions.
No hazards to be specially mentioned.

Conditions to avoid : No data available

Incompatible materials : No data available

Hazardous decomposition products : No data available

SECTION 11. TOXICOLOGICAL INFORMATION**Acute toxicity**

Not classified based on available information.

Product:Acute oral toxicity : Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation methodAcute dermal toxicity : Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method**Components:****PEG-Interferon-alpha2A:**Acute toxicity (other routes of administration) : No-observed-effect level (cynomolgus monkey): 0.3 mg/kg
Application Route: i.v.No-observed-effect level (cynomolgus monkey): 6.75 mg/kg
Application Route: s.c.**Benzenemethanol:**

Acute oral toxicity : LD50 Oral (Rat): 1,230 mg/kg

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

Version	Revision Date:	Date of last issue: 06-10-2017
0.0	10-21-2020	Date of first issue: 12-05-2015

LD50 Oral (Mouse): 1,360 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 4,178 mg/l
 Exposure time: 4 h
 Test atmosphere: vapor
 Method: OECD Test Guideline 403
 GLP: yes

Acute dermal toxicity : LD50 Dermal (Rabbit): 2,000 mg/kg

Sodium chloride (NaCl):

Acute oral toxicity : LD50 Oral (Rat): 3,000 mg/kg

LD50 Oral (Mouse): 4,000 mg/kg

Acute inhalation toxicity : Acute toxicity estimate: > 30 mg/l
 Test atmosphere: dust/mist
 Method: Expert judgment

Acute dermal toxicity : LD50 Dermal (Rabbit): > 10,000 mg/kg

Sodium acetate trihydrate:

Acute oral toxicity : LD50 (Rat): 3,530 mg/kg

LD50 (Mouse): 4,960 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 30 mg/l
 Exposure time: 1 h
 Test atmosphere: dust/mist

Acute dermal toxicity : LD50 (Rabbit): > 10,000 mg/kg

Sorbitan, mono-(9Z)-9-octadecenoate, poly(oxy-1,2-ethanediyl) derivs.:

Acute oral toxicity : LD50 Oral (Rat): 63,840 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Components:**Benzenemethanol:**

Remarks : This information is not available.

Sodium chloride (NaCl):

Species : Rabbit
 Result : No skin irritation

Sodium acetate trihydrate:

Remarks : This information is not available.

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

Version
0.0

Revision Date:
10-21-2020

Date of last issue: 06-10-2017
Date of first issue: 12-05-2015

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Benzenemethanol:

Remarks : This information is not available.

Sodium chloride (NaCl):

Species : Rabbit
Result : No eye irritation

Sodium acetate trihydrate:

Remarks : This information is not available.

Respiratory or skin sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Components:

Sodium chloride (NaCl):

Remarks : This information is not available.

Germ cell mutagenicity

Not classified based on available information.

Components:

PEG-Interferon-alpha2A:

Genotoxicity in vitro : Result: negative
Remarks: In vitro tests did not show mutagenic effects

Sodium chloride (NaCl):

Genotoxicity in vitro : Test Type: Micronucleus test
Test system: mammalian cells
Method: Mutagenicity (micronucleus test)
Result: negative

Test Type: Ames test
Result: negative

Carcinogenicity

Not classified based on available information.

Components:

Benzenemethanol:

Remarks : No ingredient of this product present at levels greater than or

PEGASYS(R) Prefilled Syringe (180 mcg/0.5 ml)
Version
0.0Revision Date:
10-21-2020Date of last issue: 06-10-2017
Date of first issue: 12-05-2015

equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

Sorbitan, mono-(9Z)-9-octadecenoate, poly(oxy-1,2-ethanediyl) derivs.:

Remarks : No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

IARC No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

NTP No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity

Not classified based on available information.

STOT-single exposure

Not classified based on available information.

Components:
Benzenemethanol:

Assessment : The substance or mixture is not classified as specific target organ toxicant, single exposure.

Sodium acetate trihydrate:

Assessment : The substance or mixture is not classified as specific target organ toxicant, single exposure.

Sorbitan, mono-(9Z)-9-octadecenoate, poly(oxy-1,2-ethanediyl) derivs.:

Assessment : The substance or mixture is not classified as specific target organ toxicant, single exposure.

STOT-repeated exposure

Not classified based on available information.

Components:
Benzenemethanol:

Assessment : The substance or mixture is not classified as specific target organ toxicant, repeated exposure.

Sodium acetate trihydrate:

Assessment : The substance or mixture is not classified as specific target organ toxicant, repeated exposure.

Sorbitan, mono-(9Z)-9-octadecenoate, poly(oxy-1,2-ethanediyl) derivs.:

Assessment : The substance or mixture is not classified as specific target

PEGASYS(R) Prefilled Syringe (180 mcg/0.5 ml)Version
0.0Revision Date:
10-21-2020Date of last issue: 06-10-2017
Date of first issue: 12-05-2015

organ toxicant, repeated exposure.

Aspiration toxicity

Not classified based on available information.

Components:**Benzenemethanol:**

No data available

Sodium acetate trihydrate:

No data available

Sorbitan, mono-(9Z)-9-octadecenoate, poly(oxy-1,2-ethanediyl) derivs.:

No data available

SECTION 12. ECOLOGICAL INFORMATION**Components:****PEG-Interferon-alpha2A:**

Toxicity to fish : LC50 (Cyprinus carpio (Carp)): > 300 mg/l
Exposure time: 96 h
Test Type: semi-static test
Method: OECD Test Guideline 203
GLP: yes

NOEC (Cyprinus carpio (Carp)): 300 mg/l
Exposure time: 96 h
Test Type: semi-static test
Method: OECD Test Guideline 203
GLP: yes

Toxicity to daphnia and other : LC50 (Daphnia magna (Water flea)): > 300 mg/l
aquatic invertebrates : Exposure time: 48 h
Test Type: semi-static test
Method: OECD Test Guideline 202
GLP: yes

NOEC (Daphnia magna (Water flea)): 300 mg/l
Exposure time: 48 h
Test Type: semi-static test
Method: OECD Test Guideline 202
GLP: yes

Toxicity to microorganisms : (activated sludge): 3.3 mg/l
Exposure time: 28 d
Method: OECD Test Guideline 301D
GLP: yes

Remarks: Barely inhibitory on aerobic bacterial respiration

Benzenemethanol:

PEGASYS(R) Prefilled Syringe (180 mcg/0.5 ml)
Version
0.0Revision Date:
10-21-2020Date of last issue: 06-10-2017
Date of first issue: 12-05-2015

- Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 460 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203
- LC50 (Oncorhynchus mykiss (rainbow trout)): 315 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203
- LC50 (Lepomis macrochirus (Bluegill sunfish)): 10 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203
- Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 400 mg/l
Exposure time: 24 h
- EC0 (Daphnia magna (Water flea)): 369 mg/l
Exposure time: 48 h
- Toxicity to algae : EC0 (Desmodesmus subspicatus (green algae)): 640 mg/l
Exposure time: 96 h
- Toxicity to microorganisms : EC10 (Pseudomonas putida): 658 mg/l
Exposure time: 48 h

Ecotoxicology Assessment

- Acute aquatic toxicity : Toxic to aquatic life.
- Chronic aquatic toxicity : This product has no known ecotoxicological effects.
- Toxicity Data on Soil : Not expected to adsorb on soil.
- Other organisms relevant to the environment : No data available

Sodium chloride (NaCl):

- Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 7,650 mg/l
Exposure time: 96 h
- Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 1,000 mg/l
Exposure time: 48 h

Ecotoxicology Assessment

- Acute aquatic toxicity : This product has no known ecotoxicological effects.
- Chronic aquatic toxicity : This product has no known ecotoxicological effects.
- Toxicity Data on Soil : Not expected to adsorb on soil.
- Other organisms relevant to the environment : No data available

Sodium acetate trihydrate:

- Toxicity to fish : LC50 (Lepomis macrochirus (Bluegill sunfish)): 5,000 mg/l

PEGASYS(R) Prefilled Syringe (180 mcg/0.5 ml)
Version
0.0Revision Date:
10-21-2020Date of last issue: 06-10-2017
Date of first issue: 12-05-2015

Exposure time: 24 h

LC50 (Leuciscus idus (Golden orfe)): > 1,000 mg/l
Exposure time: 48 hToxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 1,000 mg/l
Exposure time: 48 hToxicity to microorganisms : EC50 (Pseudomonas putida): 7,200 mg/l
Exposure time: 18 hEC50 (Photobacterium phosphoreum): 22,500 mg/l
Exposure time: 0.25 h**Ecotoxicology Assessment**

Toxicity Data on Soil : Not expected to adsorb on soil.

Other organisms relevant to the environment : No data available

Sorbitan, mono-(9Z)-9-octadecenoate, poly(oxy-1,2-ethanediyl) derivs.:**Ecotoxicology Assessment**

Toxicity Data on Soil : Not expected to adsorb on soil.

Other organisms relevant to the environment : No data available

Persistence and degradability**Components:****PEG-Interferon-alpha2A:**Biodegradability : Concentration: 3.3 mg/l
Result: Not readily biodegradable.
Biodegradation: <= 22 %
Exposure time: 28 d
Method: OECD Test Guideline 301D
GLP: yes**Benzenemethanol:**Biodegradability : Biodegradation: 100 %
Exposure time: 2 d
Method: OECD Test Guideline 302B**Sodium chloride (NaCl):**

Biodegradability : Remarks: The methods for determining biodegradability are not applicable to inorganic substances.

Sodium acetate trihydrate:Biodegradability : Biodegradation: 99 %
Exposure time: 28 d

PEGASYS(R) Prefilled Syringe (180 mcg/0.5 ml)Version
0.0Revision Date:
10-21-2020Date of last issue: 06-10-2017
Date of first issue: 12-05-2015**Bioaccumulative potential****Components:****PEG-Interferon-alpha2A:**Partition coefficient: n-
octanol/water : Remarks: No data available**Benzenemethanol:**Partition coefficient: n-
octanol/water : log Pow: 1.10**Sodium chloride (NaCl):**Partition coefficient: n-
octanol/water : Remarks: No data available**Sodium acetate trihydrate:**Partition coefficient: n-
octanol/water : log Pow: -4.22**Sorbitan, mono-(9Z)-9-octadecenoate, poly(oxy-1,2-ethanediyl) derivs.:**Partition coefficient: n-
octanol/water : Remarks: No data available**Water:**Partition coefficient: n-
octanol/water : Remarks: No data available**Mobility in soil**

No data available

Other adverse effects**Product:**Ozone-Depletion Potential : Regulation: 40 CFR Protection of Environment; Part 82 Protection of Stratospheric Ozone - CAA Section 602 Class I Substances
Remarks: This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).**Components:****Benzenemethanol:**

Additional ecological information : No data available

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

Version
0.0

Revision Date:
10-21-2020

Date of last issue: 06-10-2017
Date of first issue: 12-05-2015

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

- Waste from residues : Can be disposed as waste water, when in compliance with local regulations.

- Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.
Do not re-use empty containers.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG

Not regulated as a dangerous good

IATA-DGR

Not regulated as a dangerous good

IMDG-Code

Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable

Domestic regulation

49 CFR

Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION

EPCRA - Emergency Planning and Community Right-to-Know

CERCLA Reportable Quantity

This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards : No SARA Hazards

SARA 313 : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

Clean Air Act

This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

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

Version	Revision Date:	Date of last issue: 06-10-2017
0.0	10-21-2020	Date of first issue: 12-05-2015

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 112 (40 CFR 61).
 This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).
 The following chemical(s) are listed under the U.S. Clean Air Act Section 111 SOCM I Intermedi-ate or Final VOC's (40 CFR 60.489):

Benzenemethanol	100-51-6	>= 1 - < 5 %
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Clean Water Act

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.
 This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.
 This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

US State Regulations

Massachusetts Right To Know

Benzenemethanol	100-51-6
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Pennsylvania Right To Know

Water	7732-18-5
Benzenemethanol	100-51-6

Maine Chemicals of High Concern

Product does not contain any listed chemicals

Vermont Chemicals of High Concern

Product does not contain any listed chemicals

Washington Chemicals of High Concern

Product does not contain any listed chemicals

The ingredients of this product are reported in the following inventories:

- DSL : This product contains the following components that are not on the Canadian DSL nor NDSL.
PEG-Interferon-alpha2A
- AICS : Not in compliance with the inventory
- NZIoC : Not in compliance with the inventory
- ENCS : Not in compliance with the inventory
- ISHL : Not in compliance with the inventory
- KECI : Not in compliance with the inventory
- PICCS : Not in compliance with the inventory
- IECSC : Not in compliance with the inventory
- TCSI : Not in compliance with the inventory
- TSCA : Substance(s) not listed on TSCA inventory

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

Version
0.0

Revision Date:
10-21-2020

Date of last issue: 06-10-2017
Date of first issue: 12-05-2015

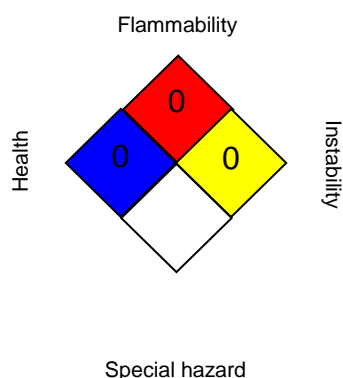
TSCA list

No substances are subject to a Significant New Use Rule.

No substances are subject to TSCA 12(b) export notification requirements.

SECTION 16. OTHER INFORMATION

NFPA:



HMIS® IV:

HEALTH	/	0
FLAMMABILITY		0
PHYSICAL HAZARD		0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations

US WEEL : USA. Workplace Environmental Exposure Levels (WEEL)
US WEEL / TWA : 8-hr TWA

AICS - Australian Inventory of Chemical Substances; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relation-

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

Version
0.0

Revision Date:
10-21-2020

Date of last issue: 06-10-2017
Date of first issue: 12-05-2015

ship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Revision Date : 10-21-2020

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

US / Z8 / 1810