according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



# **Peginterferon Alfa-2b Powder Formulation**

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 3.3 28.09.2024 20534-00027 Date of first issue: 09.10.2014

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

1.1 Product identifier

Trade name : Peginterferon Alfa-2b Powder Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Sub-

stance/Mixture

: Pharmaceutical

Recommended restrictions

on use

Not applicable

1.3 Details of the supplier of the safety data sheet

Company : MSD

Kilsheelan

Clonmel Tipperary, IE

Telephone : 353-51-601000

E-mail address of person

responsible for the SDS

EHSDATASTEWARD@msd.com

### 1.4 Emergency telephone number

+1-908-423-6000

### **SECTION 2: Hazards identification**

### 2.1 Classification of the substance or mixture

#### Classification (REGULATION (EC) No 1272/2008)

Reproductive toxicity, Category 1B H360FD: May damage fertility. May damage the

unborn child.

#### 2.2 Label elements

### Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms

Signal word : Danger

Hazard statements : H360FD May damage fertility. May damage the unborn

child.

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



# **Peginterferon Alfa-2b Powder Formulation**

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 3.3 28.09.2024 20534-00027 Date of first issue: 09.10.2014

Precautionary statements : Prevention:

P201 Obtain special instructions before use.

P280 Wear protective gloves/ protective clothing/ eye protec-

tion/ face protection.

Response:

P308 + P313 IF exposed or concerned: Get medical advice/

attention.

Storage:

P405 Store locked up.

Hazardous components which must be listed on the label:

Peginterferon Alfa-2b

#### 2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Dust contact with the eyes can lead to mechanical irritation.

Contact with dust can cause mechanical irritation or drying of the skin.

May form explosive dust-air mixture during processing, handling or other means.

### **SECTION 3: Composition/information on ingredients**

#### 3.2 Mixtures

#### Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Peginterferon Alfa-2b	215647-85-1	Repr. 1B; H360FD STOT RE 1; H372 (Gastrointestinal tract, Immune sys- tem, Cardio- vascular system, Endocrine system, Central nervous system, Liver, Res- piratory Tract, Eye)	>= 0,3 - < 1

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



# **Peginterferon Alfa-2b Powder Formulation**

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 3.3 28.09.2024 20534-00027 Date of first issue: 09.10.2014

For explanation of abbreviations see section 16.

#### **SECTION 4: First aid measures**

4.1 Description of first aid measures

General advice : In the case of accident or if you feel unwell, seek medical ad-

vice immediately.

When symptoms persist or in all cases of doubt seek medical

advice.

Protection of first-aiders : First Aid responders should pay attention to self-protection,

and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

If inhaled : If inhaled, remove to fresh air.

Get medical attention.

In case of skin contact : In case of contact, immediately flush skin with soap and plenty

of water.

Remove contaminated clothing and shoes.

Get medical attention. Wash clothing before reuse.

Thoroughly clean shoes before reuse.

In case of eye contact : If in eyes, rinse well with water.

Get medical attention if irritation develops and persists.

If swallowed : If swallowed, DO NOT induce vomiting.

Get medical attention.

Rinse mouth thoroughly with water.

4.2 Most important symptoms and effects, both acute and delayed

Risks : May damage fertility. May damage the unborn child.

Contact with dust can cause mechanical irritation or drying of

the skin.

Dust contact with the eyes can lead to mechanical irritation.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically and supportively.

### **SECTION 5: Firefighting measures**

5.1 Extinguishing media

Suitable extinguishing media : Water spray

Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



# Peginterferon Alfa-2b Powder Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 3.3 28.09.2024 20534-00027 Date of first issue: 09.10.2014

Unsuitable extinguishing

media

None known.

5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-

fighting

Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a

potential dust explosion hazard.

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod- :

ucts

Metal oxides

Phosphorus compounds Oxides of phosphorus

Carbon oxides

5.3 Advice for firefighters

Special protective equipment:

for firefighters

In the event of fire, wear self-contained breathing apparatus.

Use personal protective equipment.

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances and the surrounding environment. Use water spray to cool unopened containers.

Remove undamaged containers from fire area if it is safe to do

SO.

Evacuate area.

### **SECTION 6: Accidental release measures**

#### 6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment.

Follow safe handling advice (see section 7) and personal pro-

tective equipment recommendations (see section 8).

6.2 Environmental precautions

Environmental precautions : Avoid release to the environment.

Prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water.

Local authorities should be advised if significant spillages

cannot be contained.

#### 6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Sweep up or vacuum up spillage and collect in suitable con-

tainer for disposal.

Avoid dispersal of dust in the air (i.e., clearing dust surfaces

with compressed air).

Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.

Local or national regulations may apply to releases and dis-

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



# Peginterferon Alfa-2b Powder Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 3.3 28.09.2024 20534-00027 Date of first issue: 09.10.2014

posal of this material, as well as those materials and items employed in the cleanup of releases. You will need to deter-

mine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

#### 6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

### **SECTION 7: Handling and storage**

#### 7.1 Precautions for safe handling

Technical measures : Static electricity may accumulate and ignite suspended dust

causing an explosion.

Provide adequate precautions, such as electrical grounding

and bonding, or inert atmospheres.

Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust

ventilation.

Advice on safe handling : Do not get on skin or clothing.

Do not breathe dust. Do not swallow.

Avoid contact with eyes.

Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure as-

sessment

Keep container tightly closed.

Minimize dust generation and accumulation. Keep container closed when not in use. Keep away from heat and sources of ignition.

Take precautionary measures against static discharges.

Take care to prevent spills, waste and minimize release to the

environment.

Hygiene measures : If exposure to chemical is likely during typical use, provide eye

flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contami-

nated clothing before re-use.

#### 7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers

: Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national

regulations.

Advice on common storage : Do not store with the following product types:

Strong oxidizing agents

Self-reactive substances and mixtures

Organic peroxides

Explosives Gases

7.3 Specific end use(s)

Specific use(s) : No data available

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



# **Peginterferon Alfa-2b Powder Formulation**

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 3.3 28.09.2024 20534-00027 Date of first issue: 09.10.2014

### **SECTION 8: Exposure controls/personal protection**

#### 8.1 Control parameters

### **Occupational Exposure Limits**

Dust 5 mg/m3

Value type (Form of exposure): TWA (respirable dust)

Basis: FOR-2011-12-06-1358

10 mg/m3

Value type (Form of exposure): TWA (total dust)

Basis: FOR-2011-12-06-1358

Components	CAS-No.	Value type (Form	Control parameters	Basis
		of exposure)		
Peginterferon Alfa-	215647-85-	TWA (inhalable	0.2 μg/m3 (OEB 5)	Internal
2b	1	fraction)		

#### Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006

Substance name	End Use	Exposure routes	Potential health effects	Value
Disodium hy- drogenorthophos- phate	Workers	Inhalation	Long-term systemic effects	4,07 mg/m3
	Consumers	Inhalation	Long-term systemic effects	3,04 mg/m3

### Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006

Substance name	Environmental Compartment	Value
Disodium hydrogenorthophos-	Fresh water	0,05 mg/l
phate		-
	Marine water	0,005 mg/l
	Intermittent use/release	0,5 mg/l
	Sewage treatment plant	50 mg/l

#### 8.2 Exposure controls

#### **Engineering measures**

Minimize workplace exposure concentrations.

Apply measures to prevent dust explosions.

Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment).

If sufficient ventilation is unavailable, use with local exhaust ventilation.

### Personal protective equipment

Eye/face protection : Wear the following personal protective equipment:

Safety goggles

Equipment should conform to NS EN 166

Hand protection

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



# Peginterferon Alfa-2b Powder Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 3.3
 28.09.2024
 20534-00027
 Date of first issue: 09.10.2014

Material : Chemical-resistant gloves

Remarks : Choose gloves to protect hands against chemicals depending

on the concentration and quantity of the hazardous substance and specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Wash hands before breaks and at the

end of workday.

Skin and body protection : Select appropriate protective clothing based on chemical re-

sistance data and an assessment of the local exposure poten-

tial.

Skin contact must be avoided by using impervious protective

clothing (gloves, aprons, boots, etc).

Respiratory protection : If adequate local exhaust ventilation is not available or expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

Equipment should conform to NS EN 143

Filter type : Particulates type (P)

### **SECTION 9: Physical and chemical properties**

9.1 Information on basic physical and chemical properties

Physical state : powder

Colour : White to light yellow

Odour : No data available

Odour Threshold : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling

range

No data available

Flammability (solid, gas) : May form explosive dust-air mixture during processing, han-

dling or other means.

Flammability (liquids) : No data available

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower

flammability limit

No data available

Flash point : No data available

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



# **Peginterferon Alfa-2b Powder Formulation**

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 3.3 28.09.2024 20534-00027 Date of first issue: 09.10.2014

Auto-ignition temperature : No data available

Decomposition temperature : No data available

pH : No data available

Viscosity

Viscosity, dynamic : No data available

Viscosity, kinematic : No data available

Solubility(ies)

Water solubility : No data available

Partition coefficient: n-

octanol/water

No data available

Vapour pressure : No data available

Density : 1 g/cm<sup>3</sup>

Relative vapour density : No data available

Particle characteristics

Particle size : No data available

9.2 Other information

Explosives : Not explosive

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

Evaporation rate : No data available

Molecular weight : No data available

### **SECTION 10: Stability and reactivity**

#### 10.1 Reactivity

Not classified as a reactivity hazard.

#### 10.2 Chemical stability

Stable under normal conditions.

#### 10.3 Possibility of hazardous reactions

Hazardous reactions : May form explosive dust-air mixture during processing, han-

dling or other means.

Can react with strong oxidizing agents.

#### 10.4 Conditions to avoid

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



# **Peginterferon Alfa-2b Powder Formulation**

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 3.3 28.09.2024 20534-00027 Date of first issue: 09.10.2014

Conditions to avoid : Heat, flames and sparks.

Avoid dust formation.

10.5 Incompatible materials

Materials to avoid : Oxidizing agents

10.6 Hazardous decomposition products

No hazardous decomposition products are known.

**SECTION 11: Toxicological information** 

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Information on likely routes of : Inhalation exposure Skin contact

Ingestion

Eye contact

**Acute toxicity** 

Not classified based on available information.

**Components:** 

Peginterferon Alfa-2b:

Acute toxicity (other routes of : LD50 (Rat): > 20,1 mg/kg

administration) Application Route: Intravenous

LD50 (Monkey): > 9,8 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Components:

Peginterferon Alfa-2b:

Species : Rabbit

Result : Mild skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

**Components:** 

Peginterferon Alfa-2b:

Species : Rabbit

Result : Mild eye irritation

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



# **Peginterferon Alfa-2b Powder Formulation**

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 3.3 28.09.2024 20534-00027 Date of first issue: 09.10.2014

#### Respiratory sensitisation

Not classified based on available information.

#### Germ cell mutagenicity

Not classified based on available information.

#### **Components:**

#### Peginterferon Alfa-2b:

Genotoxicity in vitro : Test Type: reverse mutation assay

Result: negative

Test Type: Chromosomal aberration Test system: Human lymphocytes

Result: negative

Genotoxicity in vivo : Test Type: In vivo micronucleus test

Species: Mouse Result: negative

#### Carcinogenicity

Not classified based on available information.

#### Reproductive toxicity

May damage fertility. May damage the unborn child.

#### **Components:**

#### Peginterferon Alfa-2b:

Effects on fertility : Test Type: Fertility/early embryonic development

Species: Monkey, female

Application Route: Subcutaneous Dose: 0.35 milligram per kilogram Symptoms: Effect on estrous cycle

Reproductive toxicity - As-

sessment

Clear evidence of adverse effects on development, based on

animal experiments., Clear evidence of adverse effects on sexual function and fertility, based on animal experiments.

#### STOT - single exposure

Not classified based on available information.

#### STOT - repeated exposure

Not classified based on available information.

#### **Components:**

#### Peginterferon Alfa-2b:

Target Organs : Gastrointestinal tract, Immune system, Cardio-vascular sys-

tem, Endocrine system, Central nervous system, Liver, Res-

piratory Tract, Eye

Assessment : Causes damage to organs through prolonged or repeated

exposure.

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



# **Peginterferon Alfa-2b Powder Formulation**

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 3.3 28.09.2024 20534-00027 Date of first issue: 09.10.2014

#### Repeated dose toxicity

#### **Components:**

#### Peginterferon Alfa-2b:

Species : Mouse NOAEL : 0,0038 mg/kg

Application Route : Subcutaneous

Exposure time : 9 d

Species : Rat

NOAEL : 0,0042 mg/kg
Application Route : Subcutaneous

Exposure time : 30 d

Species : Monkey
LOAEL : 0,12 mg/kg
Application Route : Subcutaneous

Exposure time : 30 d

Target Organs : Blood, Bone marrow, Immune system

Species : Monkey
NOAEL : 0,015 mg/kg
LOAEL : 0,077 mg/kg
Exposure time : 3 Months

Target Organs : Respiratory Tract, Cardio-vascular system, Central nervous

system, Bone marrow

#### **Aspiration toxicity**

Not classified based on available information.

#### 11.2 Information on other hazards

#### **Endocrine disrupting properties**

### **Product:**

Assessment : The substance/mixture does not contain components consid-

ered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at

levels of 0.1% or higher.

#### **Experience with human exposure**

#### **Components:**

#### Peginterferon Alfa-2b:

Inhalation : Symptoms: flu-like symptoms, Gastrointestinal disturbance,

mental depression, tingling

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



# Peginterferon Alfa-2b Powder Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 3.3
 28.09.2024
 20534-00027
 Date of first issue: 09.10.2014

#### **SECTION 12: Ecological information**

### 12.1 Toxicity

#### **Components:**

### Peginterferon Alfa-2b:

### **Ecotoxicology Assessment**

Acute aquatic toxicity : No data available

Chronic aquatic toxicity : No data available

#### 12.2 Persistence and degradability

#### **Components:**

#### Peginterferon Alfa-2b:

Biodegradability : Result: Readily biodegradable.

Biodegradation: 63 % Exposure time: 28 d

Method: OECD Test Guideline 301B

#### 12.3 Bioaccumulative potential

No data available

#### 12.4 Mobility in soil

No data available

### 12.5 Results of PBT and vPvB assessment

#### **Product:**

Assessment : This substance/mixture contains no components considered

to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of

0.1% or higher.

### 12.6 Endocrine disrupting properties

#### **Product:**

Assessment : The substance/mixture does not contain components consid-

ered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at

levels of 0.1% or higher.

#### 12.7 Other adverse effects

No data available

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



# Peginterferon Alfa-2b Powder Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 3.3 28.09.2024 20534-00027 Date of first issue: 09.10.2014

### **SECTION 13: Disposal considerations**

#### 13.1 Waste treatment methods

Product : Dispose of in accordance with local regulations.

According to the European Waste Catalogue, Waste Codes

are not product specific, but application specific.

Waste codes should be assigned by the user, preferably in

discussion with the waste disposal authorities.

Do not dispose of waste into sewer.

Contaminated packaging : Empty containers should be taken to an approved waste han-

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

### **SECTION 14: Transport information**

#### 14.1 UN number or ID number

ADN : Not regulated as a dangerous good
ADR : Not regulated as a dangerous good
RID : Not regulated as a dangerous good
IMDG : Not regulated as a dangerous good
IATA : Not regulated as a dangerous good

#### 14.2 UN proper shipping name

ADN : Not regulated as a dangerous good
ADR : Not regulated as a dangerous good
RID : Not regulated as a dangerous good
IMDG : Not regulated as a dangerous good
IATA : Not regulated as a dangerous good

#### 14.3 Transport hazard class(es)

ADN : Not regulated as a dangerous good
ADR : Not regulated as a dangerous good
RID : Not regulated as a dangerous good
IMDG : Not regulated as a dangerous good
IATA : Not regulated as a dangerous good

#### 14.4 Packing group

ADN : Not regulated as a dangerous good
ADR : Not regulated as a dangerous good
RID : Not regulated as a dangerous good
IMDG : Not regulated as a dangerous good

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



# Peginterferon Alfa-2b Powder Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 3.3 28.09.2024 20534-00027 Date of first issue: 09.10.2014

IATA (Cargo) : Not regulated as a dangerous good
IATA (Passenger) : Not regulated as a dangerous good

14.5 Environmental hazards

Not regulated as a dangerous good

14.6 Special precautions for user

Not applicable

14.7 Maritime transport in bulk according to IMO instruments

Remarks : Not applicable for product as supplied.

#### **SECTION 15: Regulatory information**

# 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

REACH - Restrictions on the manufacture, placing on : Not applicable

the market and use of certain dangerous substances,

mixtures and articles (Annex XVII)

REACH - Candidate List of Substances of Very High : Not applicable

Concern for Authorisation (Article 59).

REACH - List of substances subject to authorisation : Not applicable

(Annex XIV)

Regulation (EC) on substances that deplete the ozone : Not applicable

layer

Regulation (EU) 2019/1021 on persistent organic pollu- : Not applicable

tants (recast)

Regulation (EU) No 649/2012 of the European Parlia: Not applicable

ment and the Council concerning the export and import

of dangerous chemicals

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.

Not applicable

### Other regulations:

Note the Working Environment Act § 4-1 and § 4-2 on requirements for the employer to protect pregnant employees against discomfort and injury as a result of the work situation and the working environment.

Note the regulation on organization, leadership and participation, chapter 12 on the work of children and young people.

#### The components of this product are reported in the following inventories:

AICS : not determined

DSL : not determined

IECSC : not determined

### 15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



# Peginterferon Alfa-2b Powder Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 28.09.2024 20534-00027 Date of first issue: 09.10.2014 3.3

#### **SECTION 16: Other information**

Other information Items where changes have been made to the previous version

are highlighted in the body of this document by two vertical

lines.

**Full text of H-Statements** 

H360FD May damage fertility. May damage the unborn child. H372

Causes damage to organs through prolonged or repeated

exposure.

Full text of other abbreviations

Repr. Reproductive toxicity

STOT RE Specific target organ toxicity - repeated exposure

FOR-2011-12-06-1358 Norway. Occupational Exposure limits

Long term exposure limit FOR-2011-12-06-1358 /

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA -European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; 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; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; 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; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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 Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; TECI -Thailand Existing Chemicals 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

#### **Further information**

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



# **Peginterferon Alfa-2b Powder Formulation**

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 3.3 28.09.2024 20534-00027 Date of first issue: 09.10.2014

Sources of key data used to compile the Safety Data Sheet

Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-

cy, http://echa.europa.eu/

Classification of the mixture: Classification procedure:

Repr. 1B H360FD Calculation method

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 is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

NO / EN