

# SAFETY DATA SHEET

Prepared in accordance with the provisions of KKDIK Annex-2 Regulation, 23.06.2017, No: 30105



## Interferon Alfa-2b Solid Formulation

Version 3.1      Revision Date: 30.09.2023      SDS Number: 2436394-00013      Date of last issue: 04.04.2023  
Date of first issue: 09.02.2018

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

#### 1.1 Product identifier

Trade name : Interferon Alfa-2b Solid Formulation

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

Use of the Substance/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

National Poison Control Center (UZEM): 114  
Emergency: 1-908-423-6000

### SECTION 2: Hazards identification

#### 2.1 Classification of the substance or mixture

##### Classification T.R. SEA No 28848 and subsequent amendments

Reproductive toxicity, Category 1B      H360FD: May damage fertility. May damage the unborn child.  
Specific target organ toxicity - repeated exposure, Category 2      H373: May cause damage to organs through prolonged or repeated exposure.

#### 2.2 Label elements

##### Labelling T.R. SEA No 28848 and subsequent amendments

Hazard pictograms :



Signal word : Danger

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

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child.  
H373 May cause damage to organs through prolonged or repeated exposure.

Precautionary statements :

### Prevention:

P201 Obtain special instructions before use.  
P260 Do not breathe dust.  
P280 Wear protective gloves/ protective clothing/ eye protection/ 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:  
Interferon alfa-2b

### 2.3 Other hazards

Dust contact with the eyes can lead to mechanical irritation.  
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. KKDIK Registration No.	SEA Classification	Concentration (% w/w)
Interferon alfa-2b	98530-12-2	Skin Irrit. 2; H315 Repr. 1B; H360FD STOT RE 2; H373 (Blood, Bone marrow)  specific concentration limit Repr. 1B; H360FD >= 0,001 % STOT RE 2; H373 >= 0,001 %	>= 1 - < 10

For explanation of abbreviations see section 16.

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3.1	30.09.2023	2436394-00013	Date of first issue: 09.02.2018

---

### 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 advice 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 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.  
May cause damage to organs through prolonged or repeated exposure. 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.
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### SECTION 5: Firefighting measures

#### 5.1 Extinguishing media

- Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical
- Unsuitable extinguishing media : None known.

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## Interferon Alfa-2b Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
3.1	30.09.2023	2436394-00013	Date of first issue: 09.02.2018

---

### 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 products : Carbon oxides  
Nitrogen oxides (NOx)  
Metal oxides  
Phosphorus compounds  
Oxides of phosphorus  
Carbon dioxide (CO<sub>2</sub>)

### 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 methods : Use extinguishing measures that are appropriate to local circumstances 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.

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## 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 protective 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 container 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 disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.

# SAFETY DATA SHEET

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## Interferon Alfa-2b Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
3.1	30.09.2023	2436394-00013	Date of first issue: 09.02.2018

---

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.

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## SECTION 7: Handling and storage

### 7.1 Precautions for safe handling

- |                         |   |   |
|-------------------------|---|---|
| Technical measures      | : | Static electricity may accumulate and ignite suspended dust causing an explosion.<br>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.<br>Do not breathe dust.<br>Do not swallow.<br>Avoid contact with eyes.<br>Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment<br>Keep container tightly closed.<br>Minimize dust generation and accumulation.<br>Keep container closed when not in use.<br>Keep away from heat and sources of ignition.<br>Take precautionary measures against static discharges.<br>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 contaminated clothing before re-use.<br>The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.  |

### 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:<br>Strong oxidizing agents<br>Self-reactive substances and mixtures<br>Organic peroxides<br>Explosives<br>Gases |

# SAFETY DATA SHEET

Prepared in accordance with the provisions of KKDIK Annex-2 Regulation, 23.06.2017, No: 30105



## Interferon Alfa-2b Solid Formulation

Version 3.1      Revision Date: 30.09.2023      SDS Number: 2436394-00013      Date of last issue: 04.04.2023  
Date of first issue: 09.02.2018

### 7.3 Specific end use(s)

Specific use(s) : No data available

## SECTION 8: Exposure controls/personal protection

### 8.1 Control parameters

#### Occupational Exposure Limits

Dust      15 mg/m<sup>3</sup>  
Value type (Form of exposure): ZOAD/TWA (Total dust)  
Basis: TR OEL DU  
Further information: Allowable occupational exposure limit values of mineral dusts

5 mg/m<sup>3</sup>  
Value type (Form of exposure): ZOAD/TWA (Respirable part)  
Basis: TR OEL DU  
Further information: Allowable occupational exposure limit values of mineral dusts

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Interferon alfa-2b	98530-12-2	TWA	0.2 µg/m <sup>3</sup> (OEB 5)	Internal
		Wipe limit	2 µg/100 cm <sup>2</sup>	Internal

#### Derived No Effect Level (DNEL) :

Substance name	End Use	Exposure routes	Potential health effects	Value
Disodium hydrogenorthophosphate	Workers	Inhalation	Long-term systemic effects	4,07 mg/m <sup>3</sup>
	Consumers	Inhalation	Long-term systemic effects	3,04 mg/m <sup>3</sup>

#### Predicted No Effect Concentration (PNEC) :

Substance name	Environmental Compartment	Value
Disodium hydrogenorthophosphate	Fresh water	0,05 mg/l
	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

Use closed processing systems or containment technologies to control at source (e.g., glove boxes/isolators) and to prevent leakage of compounds into the workplace.  
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.  
No open handling permitted.

# SAFETY DATA SHEET

Prepared in accordance with the provisions of KKDIK Annex-2 Regulation, 23.06.2017, No: 30105



## Interferon Alfa-2b Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
3.1	30.09.2023	2436394-00013	Date of first issue: 09.02.2018

Totally enclosed processes and materials transport systems are required. Operations require the use of appropriate containment technology designed to prevent leakage of compounds into the workplace.

### Personal protective equipment

Eye/face protection	:	Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.
Hand protection	:	
Material	:	Chemical-resistant gloves
Remarks	:	Consider double gloving.
Skin and body protection	:	Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.
Respiratory protection	:	If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Equipment should conform to TS EN 143
Filter type	:	Particulates type (P)

## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

Appearance	:	powder
Colour	:	White to light yellow
Odour	:	No data available
Odour Threshold	:	No data available
pH	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	Not applicable
Evaporation rate	:	Not applicable
Flammability (solid, gas)	:	May form explosive dust-air mixture during processing, handling or other means.
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower	:	No data available

# SAFETY DATA SHEET

Prepared in accordance with the provisions of KKDIK Annex-2 Regulation, 23.06.2017, No: 30105



## Interferon Alfa-2b Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
3.1	30.09.2023	2436394-00013	Date of first issue: 09.02.2018

---

flammability limit

Vapour pressure : Not applicable

Relative vapour density : Not applicable

Relative density : No data available

Density : No data available

Solubility(ies)

Water solubility : No data available

Partition coefficient: n-octanol/water : Not applicable

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, kinematic : Not applicable

Explosive properties : Not explosive

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

### 9.2 Other information

Flammability (liquids) : No data available

Particle size : No data available

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## 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, handling or other means.  
Can react with strong oxidizing agents.

### 10.4 Conditions to avoid

Conditions to avoid : Heat, flames and sparks.  
Avoid dust formation.

### 10.5 Incompatible materials

Materials to avoid : Oxidizing agents



# SAFETY DATA SHEET

Prepared in accordance with the provisions of KKDIK Annex-2 Regulation, 23.06.2017, No: 30105



## Interferon Alfa-2b Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
3.1	30.09.2023	2436394-00013	Date of first issue: 09.02.2018

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### 10.6 Hazardous decomposition products

No hazardous decomposition products are known.

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## SECTION 11: Toxicological information

### 11.1 Information on toxicological effects

Information on likely routes of exposure : Inhalation  
Skin contact  
Ingestion  
Eye contact

#### Acute toxicity

Not classified based on available information.

#### Skin corrosion/irritation

Not classified based on available information.

#### Components:

##### Interferon alfa-2b:

Species : Rat  
Result : Skin irritation

#### Serious eye damage/eye irritation

Not classified based on available information.

#### Components:

##### Interferon alfa-2b:

Species : Rabbit  
Remarks : slight irritation

#### Respiratory or skin sensitisation

##### Skin sensitisation

Not classified based on available information.

##### Respiratory sensitisation

Not classified based on available information.

##### Germ cell mutagenicity

Not classified based on available information.

#### Components:

##### Interferon alfa-2b:

Genotoxicity in vitro : Test Type: Chromosome aberration test in vitro  
Result: negative  
Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative  
Genotoxicity in vivo : Test Type: Micronucleus test

# SAFETY DATA SHEET

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## Interferon Alfa-2b Solid Formulation

Version 3.1      Revision Date: 30.09.2023      SDS Number: 2436394-00013      Date of last issue: 04.04.2023  
Date of first issue: 09.02.2018

---

Species: Mouse  
Result: negative  
Remarks: Based on data from similar materials

### **Carcinogenicity**

Not classified based on available information.

### **Reproductive toxicity**

May damage fertility. May damage the unborn child.

### **Components:**

#### **Interferon alfa-2b:**

Effects on fertility : Test Type: Fertility/early embryonic development  
Species: Monkey  
Fertility: LOAEL: 3,8 µg/kg  
Result: menstrual irregularities  
Remarks: Abortion

Effects on foetal development : Test Type: Fertility/early embryonic development  
Species: Monkey  
Developmental Toxicity: LOAEL: 3,8 µg/kg body weight  
Result: Embryo-lethal effects

Reproductive toxicity - Assessment : May damage fertility. May damage the unborn child.

### **STOT - single exposure**

Not classified based on available information.

### **STOT - repeated exposure**

May cause damage to organs through prolonged or repeated exposure.

### **Components:**

#### **Interferon alfa-2b:**

Target Organs : Blood, Bone marrow  
Assessment : May cause damage to organs through prolonged or repeated exposure.

### **Repeated dose toxicity**

### **Components:**

#### **Interferon alfa-2b:**

Species : Monkey  
NOAEL : 0,095 mg/kg  
Application Route : Intramuscular  
Exposure time : 1 Months  
Remarks : No significant adverse effects were reported

Species : Rat  
NOAEL : 0,38 mg/kg  
Application Route : Subcutaneous

# SAFETY DATA SHEET

Prepared in accordance with the provisions of KKDIK Annex-2 Regulation, 23.06.2017, No: 30105



## Interferon Alfa-2b Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
3.1	30.09.2023	2436394-00013	Date of first issue: 09.02.2018

---

Exposure time : 3 Months  
Remarks : No significant adverse effects were reported

Species : Mouse  
NOAEL : 0,076 mg/kg  
Application Route : Intraperitoneal  
Exposure time : 9 d  
Remarks : No significant adverse effects were reported

Species : Monkey  
LOAEL : 0,38 mg/kg  
Application Route : Intramuscular  
Exposure time : 3 Months  
Target Organs : Blood, Bone marrow  
Remarks : Significant toxicity observed in testing

### Aspiration toxicity

Not classified based on available information.

### Experience with human exposure

#### Components:

#### Interferon alfa-2b:

Skin contact : Symptoms: The most common side effects are:, flu-like symptoms, Fever, chills, Fatigue

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## SECTION 12: Ecological information

### 12.1 Toxicity

No data available

### 12.2 Persistence and degradability

No data available

### 12.3 Bioaccumulative potential

No data available

### 12.4 Mobility in soil

No data available

### 12.5 Results of PBT and vPvB assessment

Not relevant

### 12.6 Other adverse effects

No data available

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## 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

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# SAFETY DATA SHEET

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## Interferon Alfa-2b Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
3.1	30.09.2023	2436394-00013	Date of first issue: 09.02.2018

---

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 handling site for recycling or disposal.  
If not otherwise specified: Dispose of as unused product.

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### SECTION 14: Transport information

#### 14.1 UN 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  
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

# SAFETY DATA SHEET

Prepared in accordance with the provisions of KKDIK Annex-2 Regulation, 23.06.2017, No: 30105



## Interferon Alfa-2b Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
3.1	30.09.2023	2436394-00013	Date of first issue: 09.02.2018

### 14.6 Special precautions for user

Not applicable

### 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

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

KKDIK (30105 (Bis)) - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex 17) : Not applicable  
Regulation on Persistent Organic Pollutants (Number 30595 and subsequent amendments published) : Not applicable  
Regulation on prevention of major industrial accidents. Reg number 30702 : Not applicable

#### Other regulations:

T.R. Regulation on Classification, Labeling and Packaging of Substances and Mixtures, dated December 11, 2013 and numbered 28848 from the Ministry of Environment and Urbanization and the subsequent amendments published.

#### 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.

## 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.  
The SDS has been prepared by: Name: Gökhan Ardiç; Contact email: sds@chemleg.com; Telephone number: +90 216 706 1307; Certificate Number: Lonca KDU 34 / 2020.08; Certificate Date: 22 September 2020; Valid Until: 22 September 2025

#### Full text of H-Statements

H315 : Causes skin irritation.  
H360FD : May damage fertility. May damage the unborn child.  
H373 : May cause damage to organs through prolonged or repeated exposure.

# SAFETY DATA SHEET

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## Interferon Alfa-2b Solid Formulation

Version 3.1      Revision Date: 30.09.2023      SDS Number: 2436394-00013      Date of last issue: 04.04.2023  
Date of first issue: 09.02.2018

**The Turkish SDS has been prepared according to the Regulation on Safety Data Sheets for Hazardous Substances and Mixtures No. 29204.**

### Full text of other abbreviations

Repr. : Reproductive toxicity  
Skin Irrit. : Skin irritation  
STOT RE : Specific target organ toxicity - repeated exposure  
TR OEL DU : Türkiye. Regulation on Dust Control. Occupational Dust Exposure Limit Values (Annex 1)  
TR OEL DU / ZOAD/TWA : Time Weighted Average Value

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

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 Agency, <http://echa.europa.eu/>

### Classification of the mixture:

Repr. 1B      H360FD

### Classification procedure:

Calculation method

# SAFETY DATA SHEET

Prepared in accordance with the provisions of KKDIK Annex-2 Regulation, 23.06.2017, No: 30105



## Interferon Alfa-2b Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
3.1	30.09.2023	2436394-00013	Date of first issue: 09.02.2018

---

STOT RE 2

H373

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.

TR / EN