

**Interferon Alfa-2b Solid Formulation**

Version 6.1      Revision Date: 30.09.2023      SDS Number: 52723-00020      Date of last issue: 04.04.2023  
Date of first issue: 02.02.2015

---

**SECTION 1. PRODUCT AND COMPANY IDENTIFICATION**

Product name : Interferon Alfa-2b Solid Formulation

**Manufacturer or supplier's details**

Company : MSD

Address : Rua Coronel Bento Soares, 530  
Cruzeiro - Sao Paulo - Brazil CEP 12730-340

Telephone : 908-740-4000

Emergency telephone : 1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.com

**Recommended use of the chemical and restrictions on use**

Recommended use : Pharmaceutical

Restrictions on use : Not applicable

---

**SECTION 2. HAZARDS IDENTIFICATION****GHS Classification in accordance with ABNT NBR 14725 Standard**

Skin irritation : Category 3

Reproductive toxicity : Category 1B

Specific target organ toxicity - repeated exposure : Category 2 (Blood, Bone marrow)

**GHS label elements in accordance with ABNT NBR 14725 Standard**

Hazard pictograms :



Signal Word : Danger

Hazard Statements : H316 Causes mild skin irritation.  
H360FD May damage fertility. May damage the unborn child.  
H373 May cause damage to organs (Blood, Bone marrow) 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.

## Interferon Alfa-2b Solid Formulation

Version 6.1      Revision Date: 30.09.2023      SDS Number: 52723-00020      Date of last issue: 04.04.2023  
 Date of first issue: 02.02.2015

**Response:**

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

P332 + P313 If skin irritation occurs: Get medical advice/ attention.

**Storage:**

P405 Store locked up.

**Other hazards which do not result in classification**

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**

Substance / Mixture : Mixture

**Components**

Chemical name	CAS-No.	Classification	Concentration (% w/w)
Interferon alfa-2b	98530-12-2	Skin irritation, Category 2 Reproductive toxicity, Category 1B Specific target organ toxicity - repeated exposure (Blood, Bone marrow), Category 2	>= 1 -< 5

**SECTION 4. 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.

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.

Most important symptoms and effects, both acute and delayed : Causes mild skin irritation.  
May damage fertility. May damage the unborn child.  
May cause damage to organs through prolonged or repeated exposure.

## Interferon Alfa-2b Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
6.1	30.09.2023	52723-00020	Date of first issue: 02.02.2015

Protection of first-aiders	:	Dust contact with the eyes can lead to mechanical irritation. 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).
Notes to physician	:	Treat symptomatically and supportively.

**SECTION 5. FIRE-FIGHTING MEASURES**

Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO <sub>2</sub> ) Dry chemical
Unsuitable extinguishing media	:	None known.
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 (NO <sub>x</sub> ) Metal oxides Phosphorus compounds Oxides of phosphorus Carbon dioxide (CO <sub>2</sub> )
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.
Special protective equipment for fire-fighters	:	In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

**SECTION 6. ACCIDENTAL RELEASE MEASURES**

Personal precautions, protective equipment and emergency procedures	:	Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
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.
Methods and materials for containment and 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

## Interferon Alfa-2b Solid Formulation

Version 6.1      Revision Date: 30.09.2023      SDS Number: 52723-00020      Date of last issue: 04.04.2023  
 Date of first issue: 02.02.2015

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.

Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

### SECTION 7. HANDLING AND STORAGE

- 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 assessment  
 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 contaminated clothing before re-use.  
 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.
- Conditions for safe storage : Keep in properly labeled containers.  
 Store locked up.  
 Keep tightly closed.  
 Store in accordance with the particular national regulations.
- Materials to avoid : Do not store with the following product types:  
 Strong oxidizing agents  
 Self-reactive substances and mixtures  
 Organic peroxides  
 Explosives  
 Gases

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Ingredients with workplace control parameters

Components	CAS-No.	Value type	Control parame-	Basis
------------	---------	------------	-----------------	-------

## Interferon Alfa-2b Solid Formulation

Version 6.1      Revision Date: 30.09.2023      SDS Number: 52723-00020      Date of last issue: 04.04.2023  
 Date of first issue: 02.02.2015

		(Form of exposure)	ters / Permissible concentration	
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

**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. 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**

Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type : Particulates type

Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

Eye 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.

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.

**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance : powder

Color : White to light yellow

Odor : No data available

Odor Threshold : No data available

pH : No data available

Melting point/freezing point : No data available

**Interferon Alfa-2b Solid Formulation**

Version 6.1      Revision Date: 30.09.2023      SDS Number: 52723-00020      Date of last issue: 04.04.2023  
Date of first issue: 02.02.2015

---

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.

Flammability (liquids) : No data available

Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

Vapor pressure : Not applicable

Relative vapor 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

Autoignition 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.

Particle size : No data available

---

**SECTION 10. STABILITY AND REACTIVITY**

Reactivity : Not classified as a reactivity hazard.

Chemical stability : Stable under normal conditions.

Possibility of hazardous reactions : May form explosive dust-air mixture during processing, handling or other means.  
Can react with strong oxidizing agents.

**Interferon Alfa-2b Solid Formulation**

Version 6.1      Revision Date: 30.09.2023      SDS Number: 52723-00020      Date of last issue: 04.04.2023  
Date of first issue: 02.02.2015

---

Conditions to avoid : Heat, flames and sparks.  
Avoid dust formation.  
Incompatible materials : Oxidizing agents  
Hazardous decomposition products : No hazardous decomposition products are known.

---

**SECTION 11. TOXICOLOGICAL INFORMATION**

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

**Acute toxicity**

Not classified based on available information.

**Skin corrosion/irritation**

Causes mild skin irritation.

**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 sensitization****Skin sensitization**

Not classified based on available information.

**Respiratory sensitization**

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

## Interferon Alfa-2b Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
6.1	30.09.2023	52723-00020	Date of first issue: 02.02.2015

---

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 fetal 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 (Blood, Bone marrow) 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  
 Exposure time : 3 Months  
 Remarks : No significant adverse effects were reported



**Interferon Alfa-2b Solid Formulation**

Version 6.1      Revision Date: 30.09.2023      SDS Number: 52723-00020      Date of last issue: 04.04.2023  
Date of first issue: 02.02.2015

---

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

---

**SECTION 12. ECOLOGICAL INFORMATION****Ecotoxicity**

No data available

**Persistence and degradability**

No data available

**Bioaccumulative potential**

No data available

**Mobility in soil**

No data available

**Other adverse effects**

No data available

---

**SECTION 13. DISPOSAL CONSIDERATIONS****Disposal methods**

Waste from residues : Do not dispose of waste into sewer.  
Dispose of in accordance with local regulations.  
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.

---

**SECTION 14. TRANSPORT INFORMATION****International Regulations**

**Interferon Alfa-2b Solid Formulation**

Version 6.1      Revision Date: 30.09.2023      SDS Number: 52723-00020      Date of last issue: 04.04.2023  
Date of first issue: 02.02.2015

---

**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 for product as supplied.

**Domestic regulation****ANTT**

Not regulated as a dangerous good

**Special precautions for user**

Not applicable

---

**SECTION 15. REGULATORY INFORMATION****Safety, health and environmental regulations/legislation specific for the substance or mixture**

National List of Carcinogenic Agents for Humans - (LINACH) : Not applicable

Brazil. List of chemicals controlled by the Federal Police : Not applicable

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

AICS : not determined

DSL : not determined

IECSC : not determined

---

**SECTION 16. OTHER INFORMATION**Revision Date : 30.09.2023  
Date format : dd.mm.yyyy**Further information**Sources of key data used to compile the Material Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>**Full text of other abbreviations**

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR -

**Interferon Alfa-2b Solid Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
6.1	30.09.2023	52723-00020	Date of first issue: 02.02.2015

---

Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); 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; ERG - Emergency Response Guide; 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; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; 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 Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; 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; WHMIS - Workplace Hazardous Materials Information System

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.

BR / Z8