 SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Interferon Alfa-2b Solid Formulation

Manufacturer or supplier’s details

Company name of supplier : MSD
Address : Avenida 16 de Septiembre No. 301 Xaltocan - Xochimilco Mexico 16090
Telephone : 52 55 57284444
Telefax : 908-735-1496
Emergency telephone : 1-908-423-6000
E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use
Recommended use : Pharmaceutical

 SECTION 2. HAZARDS IDENTIFICATION

GHS Classification

Skin irritation : Category 3
Reproductive toxicity : Category 1B
Specific target organ toxicity - repeated exposure : Category 2 (Blood, Bone marrow)

GHS label elements

Hazard pictograms : [Image]

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.
P202 Do not handle until all safety precautions have been read and understood.
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.
P332 + P313 IF skin irritation occurs: Get medical advice/ attention.
SAFETY DATA SHEET
Interferon Alfa-2b Solid Formulation

Storage:
P405 Store locked up.

Disposal:
P501 Dispose of contents/container to an approved waste disposal plant.

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

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mixture</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interferon alfa-2b</td>
<td>98530-12-2</td>
<td>&gt;= 1 - &lt; 5</td>
</tr>
</tbody>
</table>

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.
Dust contact with the eyes can lead to mechanical irritation.

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).

Notes to physician: Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media: Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
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 (NOx)
- Metal oxides
- Phosphorus compounds
- Oxides of phosphorus
- Carbon dioxide (CO2)

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 and personal protective equipment recommendations.

Environmental precautions:
- Discharge into the environment must be avoided.
- Prevent further leakage or spillage if safe to do so.
- Retain and dispose of contaminated wash water.
- Local authorities should be advised if significant spills 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 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
  - Organic peroxides
  - Explosives
  - Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interferon alfa-2b</td>
<td>98530-12-2</td>
<td>TWA</td>
<td>0.2 µg/m³ (OEB 5)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>2 µg/100 cm²</td>
<td>Internal</td>
</tr>
</tbody>
</table>

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**

<table>
<thead>
<tr>
<th>Respiratory protection</th>
<th>If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Filter type</td>
<td>Particulates type</td>
</tr>
<tr>
<td>Hand protection</td>
<td></td>
</tr>
<tr>
<td>Material</td>
<td>Chemical-resistant gloves</td>
</tr>
</tbody>
</table>

**Remarks**

- Consider double gloving.
- 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.

**Eye protection**

- Wear safety glasses with side shields or 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 |
| 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. |
**SAFETY DATA SHEET**

**Interferon Alfa-2b Solid Formulation**

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue: 24.04.2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.2</td>
<td>09/13/2019</td>
<td>52735-00013</td>
<td>Date of first issue: 02.02.2015</td>
</tr>
</tbody>
</table>

- **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.
- **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
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: Embryolethal 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

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 : 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**

**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

**NOM-002-SCT**
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**

Federal Law for the control of chemical precursors, essential chemical products and machinery for producing capsules, tablets and pills.

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

- **AICS**: not determined
- **DSL**: not determined
- **IECSC**: not determined

### SECTION 16. OTHER INFORMATION

**Full text of other abbreviations**

AICS - Australian Inventory of Chemical Substances; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - 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 Tempera-
SAFETY DATA SHEET

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</tbody>
</table>

Sources of key data used to compile the Material Safety Data Sheet:

Revision Date: 09/13/2019

The information is considered as correct, but not exhaustive, and will be used only as a guide, which is based in the current knowledge of the substance or mixture, and is applicable to proper safety precautions for the product.

MX / Z8