SAFETY DATA SHEET
according to the OSHA Hazard Communication Standard

Peginterferon Alfa-2b Powder Formulation

SECTION 1. IDENTIFICATION

Product name: Peginterferon Alfa-2b Powder Formulation

Manufacturer or supplier’s details
Company name of supplier: Merck & Co., Inc
Address: 126 E. Lincoln Avenue
Rahway, New Jersey U.S.A. 07065
Telephone: 908-740-4000
Emergency telephone: 1-908-423-6000
E-mail address: EHSDATASTEWARD@merck.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 the OSHA Hazard Communication Standard (29 CFR 1910.1200)
Combustible dust
Reproductive toxicity: Category 1B

GHS label elements
Hazard pictograms:

Signal Word: Danger
Hazard Statements: If small particles are generated during further processing, handling or by other means, may form combustible dust concentrations in air.
H360FD May damage fertility. May damage the unborn child.

Precautionary Statements:
Prevention:
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P280 Wear protective gloves, protective clothing, eye protection and face protection.

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

Storage:
P405 Store locked up.

Disposal:
Peginterferon Alfa-2b Powder Formulation

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sucrose</td>
<td>57-50-1</td>
<td>&gt;= 90 - &lt;= 100</td>
</tr>
<tr>
<td>Peginterferon Alfa-2b</td>
<td>215647-85-1</td>
<td>&gt;= 0.1 - &lt; 1</td>
</tr>
</tbody>
</table>

Actual concentration is withheld as a trade secret

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 soap and plenty of water. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.

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 : 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.

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)   |
| Dry chemical           |

Unsuitable extinguishing : None known.

P501 Dispose of contents and container to an approved waste disposal plant.

Other hazards
Dust contact with the eyes can lead to mechanical irritation.
Contact with dust can cause mechanical irritation or drying of the skin.
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: Metal oxides
Phosphorus compounds
Oxides of phosphorus
Carbon oxides

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 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
Safety Data Sheet

According to the OSHA Hazard Communication Standard

Peginterferon Alfa-2b Powder Formulation

Version 7.1  Revision Date: 09/26/2023  SDS Number: 20540-00025  Date of last issue: 03/20/2023  Date of first issue: 10/09/2014

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.

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

Inert or nuisance dust
- 50 Million particles per cubic foot
  Value type (Form of exposure): TWA (total dust)
  Basis: OSHA Z-3

- 15 mg/m³
  Value type (Form of exposure): TWA (total dust)
  Basis: OSHA Z-3

- 5 mg/m³
  Value type (Form of exposure): TWA (respirable fraction)
  Basis: OSHA Z-3

Dust, nuisance dust and particulates
- 15 Million particles per cubic foot
  Value type (Form of exposure): TWA (respirable fraction)
  Basis: OSHA Z-3

- 10 mg/m³
  Value type (Form of exposure): PEL (Total dust)
  Basis: CAL PEL

- 5 mg/m³
  Value type (Form of exposure): PEL (respirable dust fraction)
  Basis: CAL PEL
Components | CAS-No. | Value type (Form of exposure) | Control parameters / Permissible concentration | Basis
--- | --- | --- | --- | ---
Sucrose | 57-50-1 | TWA | 10 mg/m³ | ACGIH
| | | TWA (Respirable) | 5 mg/m³ | NIOSH REL
| | | TWA (total) | 10 mg/m³ | NIOSH REL
| | | TWA (total dust) | 15 mg/m³ | OSHA Z-1
| | | TWA (respirable fraction) | 5 mg/m³ | OSHA Z-1
Peginterferon Alfa-2b | 215647-85-1 | TWA (inhalable fraction) | 0.2 µg/m³ (OEB 5) | Internal

**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**

**Respiratory protection**
- General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn.
- Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

**Hand protection**
- Material: Chemical-resistant gloves

**Remarks**
- Choose gloves to protect hands against chemicals depending on the concentration 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.

**Eye protection**
- Wear the following personal protective equipment:
- Safety goggles

**Skin and body protection**
- Select appropriate protective clothing based on chemical resistance data and an assessment of the local exposure potential.
**Hygiene measures:**
- Skin contact must be avoided by using impervious protective clothing (gloves, aprons, boots, etc).
- 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.

**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>powder</td>
</tr>
<tr>
<td>Color</td>
<td>White to light yellow</td>
</tr>
<tr>
<td>Odor</td>
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</tr>
<tr>
<td>Odor Threshold</td>
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</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
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</tr>
<tr>
<td>Initial boiling point and boiling range</td>
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<tr>
<td>Flash point</td>
<td>No data available</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data available</td>
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<tr>
<td>Flammability (solid, gas)</td>
<td>May form explosive dust-air mixture during processing, handling or other means.</td>
</tr>
<tr>
<td>Flammability (liquids)</td>
<td>No data available</td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapor pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapor density</td>
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</tr>
<tr>
<td>Density</td>
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</tr>
<tr>
<td>Solubility(ies)</td>
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</tr>
<tr>
<td>Water solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>No data available</td>
</tr>
<tr>
<td>Autoignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
</tbody>
</table>
Viscosity
- Viscosity, dynamic: No data available
- Viscosity, kinematic: No data available

Explosive properties: Not explosive

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

Molecular weight: No data available

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.

Components:

Sucrose:
- Acute oral toxicity: LD50 (Rat): 29,700 mg/kg

Peginterferon Alfa-2b:
- Acute toxicity (other routes of administration):
  - Application Route: Intravenous
  - LD50 (Rat): > 20.1 mg/kg
  - 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 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:

Sucrose:
Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test
Result: negative

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

OSHA No component of this product present at levels greater than or equal to 0.1% is
Peginterferon Alfa-2b Powder Formulation

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 - Assessment**
  - 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.

**Target Organs**
- Gastrointestinal tract, Immune system, Cardio-vascular system, Endocrine system, Central nervous system, Liver, Respiratory Tract, Eye

- **Assessment**
  - Causes damage to organs through prolonged or repeated exposure.

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

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<td>20540-00025</td>
<td>03/20/2023</td>
<td>10/09/2014</td>
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</tbody>
</table>

- **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.

**Experience with human exposure**

**Components:**

**Peginterferon Alfa-2b:**
- **Inhalation**: Symptoms: flu-like symptoms, Gastrointestinal disturbance, mental depression, tingling

**SECTION 12. ECOLOGICAL INFORMATION**

**Ecotoxicity**

**Components:**

**Peginterferon Alfa-2b:**

**Ecotoxicology Assessment**
- **Acute aquatic toxicity**: No data available
- **Chronic aquatic toxicity**: No data available

**Persistence and degradability**

**Components:**

**Peginterferon Alfa-2b:**
- **Biodegradability**: Result: Readily biodegradable.
  - Biodegradation: 63 %
  - Exposure time: 28 d
  - Method: OECD Test Guideline 301B

**Bioaccumulative potential**

**Components:**

**Sucrose:**
- Partition coefficient: n-octanol/water: Pow: < 1
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. 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.

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
49 CFR
Not regulated as a dangerous good

Special precautions for user
Not applicable

SECTION 15. REGULATORY INFORMATION

CERCLA Reportable Quantity
Listed substances in the product are at low enough levels to not be expected to exceed the RQ

SARA 304 Extremely Hazardous Substances Reportable Quantity
This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity
This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards
- Combustible dust
- Reproductive toxicity
SAFETY DATA SHEET
according to the OSHA Hazard Communication Standard

Peginterferon Alfa-2b Powder Formulation

Version 7.1
Revision Date: 09/26/2023
SDS Number: 20540-00025
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SARA 313
This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

US State Regulations
Pennsylvania Right To Know
Sucrose 57-50-1
Disodium hydrogenorthophosphate 7558-79-4

California List of Hazardous Substances
Disodium hydrogenorthophosphate 7558-79-4

California Permissible Exposure Limits for Chemical Contaminants
Sucrose 57-50-1

The ingredients of this product are reported in the following inventories:
AICS: not determined
DSL: not determined
IECSC: not determined

SECTION 16. OTHER INFORMATION

Further information

NFPA 704:
Flammability

Health

Instability

Special hazard

HMIS® IV:

HEALTH 0

FLAMMABILITY 3

PHYSICAL HAZARD 0

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

Full text of other abbreviations
ACGIH: USA. ACGIH Threshold Limit Values (TLV)
CAL PEL: California permissible exposure limits for chemical contaminants (Title 8, Article 107)
**SAFETY DATA SHEET**

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<tr>
<th>Source</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>NIOSH REL</td>
<td>USA. NIOSH Recommended Exposure Limits</td>
</tr>
<tr>
<td>OSHA Z-1</td>
<td>USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants</td>
</tr>
<tr>
<td>OSHA Z-3</td>
<td>USA. Occupational Exposure Limits (OSHA) - Table Z-3 Mineral Dusts</td>
</tr>
<tr>
<td>ACGIH / TWA</td>
<td>8-hour, time-weighted average</td>
</tr>
<tr>
<td>CAL PEL / PEL</td>
<td>Permissible exposure limit</td>
</tr>
<tr>
<td>NIOSH REL / TWA</td>
<td>Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek</td>
</tr>
<tr>
<td>OSHA Z-1 / TWA</td>
<td>8-hour time weighted average</td>
</tr>
<tr>
<td>OSHA Z-3 / TWA</td>
<td>8-hour time weighted average</td>
</tr>
</tbody>
</table>


**Revision Date**: 09/26/2023
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.