SAFETY DATA SHEET

Peginterferon Alfa-2b Redipen Formulation

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Peginterferon Alfa-2b Redipen Formulation

Manufacturer or supplier’s details

Company: MSD
Address: Rua Treze de Maio, 1161
Campinas, São Paulo, Brazil 13106-054
Telephone: 908-740-4000
Emergency telephone: 55 19 3758 2000
E-mail address: EHSDATASTEWARD@msd.com
Telefax: 908-735-1496

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

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification in accordance with ABNT NBR 14725 Standard
Reproductive toxicity: Category 1B

GHS label elements in accordance with ABNT NBR 14725 Standard
Hazard pictograms: 

Signal Word: Danger
Hazard Statements: H360FD May damage fertility. May damage the unborn child.
Precautionary Statements: Prevention:
P201 Obtain special instructions before use.
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.
SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peginterferon Alfa-2b</td>
<td>215647-85-1</td>
<td>Reproductive toxicity, Category 1B Specific target organ toxicity - repeated exposure (Gastrointestinal tract, Immune system, Cardiovascular system, Endocrine system, Central nervous system, Liver, Respiratory Tract, Eye), Category 1</td>
<td>&gt;= 0,1 &lt;= 1</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 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.

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 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

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 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 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.

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>Peginterferon Alfa-2b</td>
<td>215647-85-1</td>
<td>TWA (inhalable fraction)</td>
<td>0.2 µg/m³ (OEB 5)</td>
<td>Internal</td>
</tr>
</tbody>
</table>

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: 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: 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. Skin contact must be avoided by using impervious protective clothing (gloves, aprons, boots, etc.).

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: powder

Color: off-white

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: No data available

Evaporation rate: No data available

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 : No data available
Relative vapor density : No data available
Relative density : No data available
Solubility(ies)
Water solubility : soluble
Partition coefficient: n-octanol/water : No data available
Autoignition temperature : No data available
Decomposition temperature : No data available
Viscosity
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:
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:
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:

<table>
<thead>
<tr>
<th>Effect Type</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Effects on fertility</td>
<td>Test Type: Fertility/early embryonic development</td>
</tr>
<tr>
<td></td>
<td>Species: Monkey, female</td>
</tr>
<tr>
<td></td>
<td>Application Route: Subcutaneous</td>
</tr>
<tr>
<td></td>
<td>Dose: 0.35 milligram per kilogram</td>
</tr>
<tr>
<td></td>
<td>Symptoms: Effect on estrous cycle</td>
</tr>
</tbody>
</table>

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.

Components:

Peginterferon Alfa-2b:

<table>
<thead>
<tr>
<th>Target Organs</th>
<th>Description</th>
<th>Species</th>
<th>NOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gastrointestinal tract, Immune system, Cardio-vascular system, Endocrine system, Central nervous system, Liver, Respiratory Tract, Eye</td>
<td>Mouse</td>
<td>0.0038 mg/kg</td>
<td>Subcutaneous</td>
<td>9 d</td>
<td></td>
</tr>
</tbody>
</table>

Species:
Rat
Species:
Species
NOAEL:
0.0042 mg/kg
Application Route:
Subcutaneous
Exposure time:
30 d

Species:
Species
LOAEL:
0.12 mg/kg
Application Route:
Subcutaneous
Exposure time:
30 d
Target Organs:
Blood, Bone marrow, Immune system

Species:
Species
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:

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

ANTT
Not regulated as a dangerous good

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. Ordinance No. 1274 on the control and monitoring of chemicals. : Not applicable

International Regulations

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


Full text of other abbreviations
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.

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