SECTION 1. IDENTIFICATION

Product name : Interferon Alfa-2b Liquid Formulation

Manufacturer or supplier’s details

Company : MSD
Address : 855 Leandro N. Alem St., 8 Floor
           Buenos Aires, Argentina C1001AFB
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

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification

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

GHS label elements

Hazard pictograms : 

Signal Word : Danger
Hazard Statements : 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 mist or vapors.
                           P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.
                           Response:
                           P308 + P313 IF exposed or concerned: Get medical advice/ attention.
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Storage:
P405 Store locked up.

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

Other hazards which do not result in classification
None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td>m-Cresol</td>
<td>108-39-4</td>
</tr>
<tr>
<td>Interferon alfa-2b</td>
<td>98530-12-2</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: Flush eyes with water as a precaution. 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. May cause damage to organs through prolonged or repeated exposure.

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
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Version 4.4  Revision Date: 12.10.2021  SDS Number: 45269-00014  Date of last issue: 23.03.2020
Date of first issue: 07.01.2015

Unsuitable extinguishing media : None known.
Specific hazards during fire fighting : Exposure to combustion products may be a hazard to health.
Hazardous combustion products : No hazardous combustion products are known
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.
                                      Prevent spreading over a wide area (e.g., by containment or oil barriers).
                                      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 : Soak up with inert absorbent material.
                                      For large spills, provide diking or other appropriate containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate container.
                                      Clean up remaining materials from spill with suitable absorbent.
                                      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 : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
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 mist or vapors.
                                      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.
- 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
  - Organic peroxides
  - Explosives
  - Gases

### SECTION 8. EXPOSURE CONTROLS/PERSOANAL 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>m-Cresol</td>
<td>108-39-4</td>
<td>CMP</td>
<td>5 ppm</td>
<td>AR OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Further information: Skin</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Inhalable fraction and vapor)</td>
<td>20 mg/m³</td>
<td>ACGIH</td>
</tr>
<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></td>
<td>Wipe limit</td>
<td>2 µg/100 cm²</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**

**Respiratory protection:**
- No personal respiratory protective equipment normally required.

**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.

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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: liquid
Color: colorless
Odor: No data available
Odor Threshold: No data available
pH: 6.5 - 8
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): Not applicable
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
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Relative vapor density : No data available
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 : No data available
Explosive properties : Not explosive
Oxidizing properties : The substance or mixture is not classified as oxidizing.
Molecular weight : Not applicable
Particle size : Not applicable

SECTION 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.
Chemical stability : Stable under normal conditions.
Possibility of hazardous reactions : Can react with strong oxidizing agents.
Conditions to avoid : None known.
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.

Product:
Acute oral toxicity : Acute toxicity estimate: > 5.000 mg/kg
  Method: Calculation method
Acute dermal toxicity : Acute toxicity estimate: > 5.000 mg/kg
  Method: Calculation method
Components:

**m-Cresol:**

**Acute oral toxicity**
- LD50 (Rat): 121 mg/kg
- Remarks: Based on data from similar materials

**Acute inhalation toxicity**
- Assessment: Corrosive to the respiratory tract.

**Acute dermal toxicity**
- LD50 (Rabbit): 301 mg/kg
- Remarks: Based on data from similar materials

**Skin corrosion/irritation**
Not classified based on available information.

**Components:**

**m-Cresol:**

**Species**
- Rabbit

**Result**
- Corrosive after 3 minutes to 1 hour of exposure

**Interferon alfa-2b:**

**Species**
- Rat

**Result**
- Skin irritation

**Serious eye damage/eye irritation**
Not classified based on available information.

**Components:**

**m-Cresol:**

**Species**
- Rabbit

**Result**
- Irreversible effects on the eye

**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:**

**m-Cresol:**

**Genotoxicity in vitro**
- Test Type: Chromosome aberration test in vitro
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<td>4.4</td>
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<td>07.01.2015</td>
</tr>
</tbody>
</table>

Method: OECD Test Guideline 473
Result: positive

Test Type: Bacterial reverse mutation assay (AMES)
Method: OECD Test Guideline 471
Result: negative

Genotoxicity in vivo:
- Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)
  - Species: Mouse
  - Application Route: Ingestion
  - Method: OECD Test Guideline 475
  - Result: negative

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.

Components:

m-Cresol:
- Species: Mouse, males
- Application Route: Ingestion
- Exposure time: 105 weeks
- Result: equivocal
- Remarks: Based on data from similar materials
- Species: Mouse, female
- Application Route: Ingestion
- Exposure time: 106 - 107 weeks
- Result: positive
- Remarks: Based on data from similar materials

Carcinogenicity - Assessment: Weight of evidence does not support classification as a carcinogen

Reproductive toxicity
May damage fertility. May damage the unborn child.

Components:

m-Cresol:
- Effects on fertility: Test Type: Two-generation reproduction toxicity study
Species: Rat  
Application Route: Ingestion  
Result: negative

Effects on fetal development : Test Type: Prenatal development toxicity study (teratogenicity)  
Species: Rat  
Application Route: Ingestion  
Result: negative

**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:**

**m-Cresol:**

Species : Rat  
NOAEL : 150 mg/kg  
Application Route : Ingestion  
Exposure time : 13 Weeks  
Method : OECD Test Guideline 408

**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

Components:

m-Cresol:
Toxicity to fish: LC50 (Oncorhynchus mykiss (rainbow trout)): 8.6 mg/l  
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia pulex (Water flea)): > 99.5 mg/l  
Exposure time: 48 h

Toxicity to fish (Chronic toxicity): NOEC (Pimephales promelas (fathead minnow)): 1.35 mg/l  
Exposure time: 32 d  
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity): NOEC (Daphnia magna (Water flea)): 1 mg/l  
Exposure time: 21 d  
Remarks: Based on data from similar materials
Persistence and degradability

Components:

**m-Cresol:**

Biodegradability

Result: Readily biodegradable.
Biodegradation: 90 %
Exposure time: 28 d
Method: OECD Test Guideline 301D

Bioaccumulative potential

Components:

**m-Cresol:**

Bioaccumulation

Species: Leuciscus idus (Golden orfe)
Bioconcentration factor (BCF): 17 - 20

Partition coefficient: n-octanol/water

log Pow: 1,96

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.

Special precautions for user

Not applicable
SECTION 15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture

Argentina. Carcinogenic Substances and Agents Registry: Not applicable

Control of precursors and essential chemicals for the preparation of drugs: 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

Further information

Full text of other abbreviations

ACGIH / TWA: 8-hour, time-weighted average

AR OEL / CMP: TLV (Threshold Limit Value)

AllIC - 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 - 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 Existing Chemical Substances; OEL - Occupational Exposure Limit; OSHA - Occupational Safety and Health Administration; PEL - Permissible Exposure Limit; PMDA - Pharmaceuticals and Medical Devices Agency (Japan); PPB - Part per Billion; RCRA - Resource Conservation and Recovery Act; REACH - Registration, Evaluation, Authorisation and Restriction of Chemicals; Rgel - Rate of growth; Rmt - Rate of mortality; SC - Skin Irritant; SDM - Smith's Dose-Mortality Curve; SDP - Smith's Dose-Percentage Curve; SIE - Smith's Index of Effectiveness; SOA - Smith's Overall Activity; TWA - Time Weighted Average; US - United States; U.S. EPA - United States Environmental Protection Agency; UN - United Nations; United Nations Transport of Dangerous Goods; WOE - Weight of Evidence; x% - Concentration or Loading rate; Yale Slope - Smith's Overall Activity; YS - Yale Slope; Z - Statistical significance; Zcl - Clinical effect; Zre - Regulatory effect; Zto - Toxicological effect.
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.

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