SAFETY DATA SHEET
according to GB/T 16483 and GB/T 17519

Interferon Alfa-2b Liquid Formulation

Version 2.8  Revision Date: 09/13/2019  SDS Number: 42806-00011  Date of last issue: 2019/04/24  Date of first issue: 2015/01/07

1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Interferon Alfa-2b Liquid Formulation

Manufacturer or supplier’s details
Company: MSD
Address: 199 Wenhai North Road
HEDA, Hangzhou - Zhejiang Province - CHINA 310018
Telephone: 908-740-4000
Emergency telephone number: 86-571-87268110
E-mail address: EHSDATASTEWARD@msd.com

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

2. HAZARDS IDENTIFICATION

Emergency Overview
Appearance: liquid
Colour: colourless
Odour: No data available

May damage fertility. May damage the unborn child. May cause damage to organs through prolonged or repeated exposure.

GHS Classification
Reproductive toxicity: Category 1B
Specific target organ toxicity - repeated exposure: Category 2

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 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
Interferon Alfa-2b Liquid Formulation

and understood.
P260 Do not breathe mist or vapours.
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.

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

Physical and chemical hazards
Not classified based on available information.

Health hazards
May damage fertility. May damage the unborn child. May cause damage to organs through prolonged or repeated exposure.

Environmental hazards
Not classified based on available information.

Other hazards which do not result in classification
None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Mixture</th>
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</thead>
</table>

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>m-Cresol</td>
<td>108-39-4</td>
<td>&gt;= 0.1 &lt; 0.25</td>
</tr>
<tr>
<td>Interferon alfa-2b</td>
<td>98530-12-2</td>
<td>&gt;= 0.001 &lt; 0.1</td>
</tr>
</tbody>
</table>

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.

5. FIREFIGHTING MEASURES

Suitable extinguishing media:
- Water spray
- Alcohol-resistant foam
- Carbon dioxide (CO2)
- Dry chemical

Unsuitable extinguishing media:
- None known.

Specific hazards during firefighting:
- 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 firefighters:
- In the event of fire, wear self-contained breathing apparatus.
- Use personal protective equipment.

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.
- 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 dyking or other appropriate containment to keep material from spreading. If dyked 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.

7. HANDLING AND STORAGE

Handling
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 vapours or spray mist. 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.
Avoidance of contact : Oxidizing agents

Storage
Conditions for safe storage : Keep in properly labelled 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
Packaging material : Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components 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>PC-TWA</td>
<td>10 mg/m³</td>
<td>GBZ 2.1-2007</td>
</tr>
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<td></td>
<td></td>
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<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 2 µg/100 cm²</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Further information: Skin
SAFETY DATA SHEET
according to GB/T 16483 and GB/T 17519

Interferon Alfa-2b Liquid Formulation

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.
Eye/face 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, gauntletts, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.

Hand protection
Material: Chemical-resistant gloves
Remarks: Consider double gloving.

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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: liquid
Colour: colourless
Odour: No data available
Odour 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

Vapour pressure: No data available

Relative vapour 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

Auto-ignition 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

10. STABILITY AND REACTIVITY

Reactivity: Not classified as a reactivity hazard.
SAFETY DATA SHEET
according to GB/T 16483 and GB/T 17519

Interferon Alfa-2b Liquid Formulation

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.

11. TOXICOLOGICAL INFORMATION

Exposure routes:
- 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 sensitisation
Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
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
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 foetal 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 foetal 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 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

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

m-Cresol:
Toxicity to fish: LC50 (Oncorhynchus mykiss (rainbow trout)): 8.6 mg/l Exposition time: 96 h
Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia pulex (Water flea)): > 99.5 mg/l Exposition time: 48 h
Toxicity to fish (Chronic toxicity): NOEC (Pimephales promelas (fathead minnow)): 1.35 mg/l Exposition 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 Exposition time: 21 d Remarks: Based on data from similar materials

Persistence and degradability

Components:

m-Cresol:

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
Interferon Alfa-2b Liquid Formulation

Other adverse effects
No data available

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.

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.

National Regulations
GB 6944/12268
Not regulated as a dangerous good

Special precautions for user
Not applicable

15. REGULATORY INFORMATION

National regulatory information
Law on the Prevention and Control of Occupational Diseases

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

16. OTHER INFORMATION

Further information
Sources of key data used to : Internal technical data, data from raw material SDSs, OECD
Interferon Alfa-2b Liquid Formulation

Version: 2.8  Revision Date: 09/13/2019  SDS Number: 42806-00011  Date of last issue: 2019/04/24

 compile the Safety Data Sheet


Date format: yyyy/mm/dd

Full text of other abbreviations

ACGIH: USA. ACGIH Threshold Limit Values (TLV)

ACGIH / TWA: 8-hour, time-weighted average
GBZ 2.1-2007 / PC-TWA: Permissible concentration - time weighted average

AIICS - 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; ic - 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; 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

Disclaimer

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