

## Interferon Alfa-2b Liquid Formulation

Version 5.6      Revision Date: 10/01/2022      SDS Number: 42803-00016      Date of last issue: 04/09/2022  
Date of first issue: 01/07/2015

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### SECTION 1. IDENTIFICATION

Product name : Interferon Alfa-2b Liquid Formulation  
Other means of identification : No data available

#### 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


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### SECTION 2. HAZARDS IDENTIFICATION

#### GHS classification in accordance with the Hazardous Products Regulations

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

#### 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 and face protection.  
**Response:**  
P308 + P313 IF exposed or concerned: Get medical attention.  
**Storage:**  
P405 Store locked up.

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### Disposal:

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

### Other hazards

None known.

## SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

### Components

Chemical name	Common Name/Synonym	CAS-No.	Concentration (% w/w)
m-Cresol	Phenol, 3-methyl-	108-39-4	$\geq 0.1 - < 1$ *
Interferon alfa-2b	No data available	98530-12-2	$\geq 0.001 - < 0.1$ *

\* Actual concentration or concentration range 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.
- 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 (CO<sub>2</sub>)

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Unsuitable extinguishing media	:	Dry chemical 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.

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### 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.

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### 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.

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- 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  
 Self-reactive substances and mixtures  
 Organic peroxides  
 Explosives  
 Gases

## SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

## Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
m-Cresol	108-39-4	TWA	5 ppm 22 mg/m <sup>3</sup>	CA AB OEL
		TWAEV (inhalable fraction and vapour)	20 mg/m <sup>3</sup>	CA QC OEL
		TWA	10 mg/m <sup>3</sup>	CA BC OEL
		TWA (Inhalable fraction and vapor)	20 mg/m <sup>3</sup>	ACGIH
Interferon alfa-2b	98530-12-2	TWA	0.2 µg/m <sup>3</sup> (OEB 5)	Internal
		Wipe limit	2 µg/100 cm <sup>2</sup>	Internal

- 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.

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**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.

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**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

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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

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

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**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.

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**SECTION 11. TOXICOLOGICAL INFORMATION****Information on likely routes of exposure**

Inhalation  
Skin contact  
Ingestion  
Eye contact

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### Acute toxicity

Not classified based on available information.

### Product:

Acute oral toxicity : Acute toxicity estimate: > 2,000 mg/kg  
Method: Calculation method

Acute dermal toxicity : Acute toxicity estimate: > 2,000 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.

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**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  
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



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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

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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 tox- : NOEC (Pimephales promelas (fathead minnow)): 1.35 mg/l

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icity) 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

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**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.

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**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

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### Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

### Domestic regulation

#### TDG

Not regulated as a dangerous good

### Special precautions for user

Not applicable

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## SECTION 15. REGULATORY INFORMATION

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

AICS	:	not determined
DSL	:	not determined
IECSC	:	not determined

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## SECTION 16. OTHER INFORMATION

### Full text of other abbreviations

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
CA AB OEL	:	Canada. Alberta, Occupational Health and Safety Code (table 2: OEL)
CA BC OEL	:	Canada. British Columbia OEL
CA QC OEL	:	Québec. Regulation respecting occupational health and safety, Schedule 1, Part 1: Permissible exposure values for airborne contaminants
ACGIH / TWA	:	8-hour, time-weighted average
CA AB OEL / TWA	:	8-hour Occupational exposure limit
CA BC OEL / TWA	:	8-hour time weighted average
CA QC OEL / TWA	:	Time-weighted average exposure value

AIIC - 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

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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; TECl - 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

Sources of key data used to compile the Material Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

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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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