

# **Interferon Alfa-2b Liquid Formulation**

Version **Revision Date:** SDS Number: Date of last issue: 04.04.2023 30.09.2023 45269-00019 Date of first issue: 07.01.2015 4.9

#### **SECTION 1. IDENTIFICATION**

Product name Interferon Alfa-2b Liquid Formulation

Manufacturer or supplier's details

MSD Company

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 Restrictions on use : Not applicable

#### **SECTION 2. HAZARDS IDENTIFICATION**

**GHS Classification** 

Reproductive toxicity Category 1B

repeated exposure

Specific target organ toxicity - : Category 2 (Blood, Bone marrow)

**GHS** label elements

Hazard pictograms

Signal Word Danger

H360FD May damage fertility. May damage the unborn child. **Hazard Statements** 

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 protec-

tion/ face protection.



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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.

Other hazards which do not result in classification

None known.

#### **SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
m-Cresol	108-39-4	>= 0,1 -< 0,25
Interferon alfa-2b	98530-12-2	>= 0,001 -< 0,1

## **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

Remove contaminated clothing and shoes.

Get medical attention. Wash clothing before reuse.

Thoroughly clean shoes before reuse.

: 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

In case of eye contact

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).

Treat symptomatically and supportively. Notes to physician

#### **SECTION 5. FIRE-FIGHTING MEASURES**



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Suitable extinguishing media : Water spray

> Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical None known.

Unsuitable extinguishing

media

Specific hazards during fire

fighting

Hazardous combustion prod-

ucts

No hazardous combustion products are known

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

Exposure to combustion products may be a hazard to health.

cumstances 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, protec- : tive equipment and emer-

gency 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.

If sufficient ventilation is unavailable, use with local exhaust Local/Total ventilation

ventilation.



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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

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	CMP	5 ppm	AR OEL	
	Further information: Skin				
		TWA (Inhalable fraction and vapor)	20 mg/m³	ACGIH	
Interferon alfa-2b	98530-12-2	TWA	0.2 μg/m3 (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.

Personal protective equipment

Respiratory protection : No personal respiratory protective equipment normally

required.



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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



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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

## **SECTION 10. STABILITY AND REACTIVITY**

Reactivity : Not classified as a reactivity hazard. Chemical stability : Stable under normal conditions.

Possibility of hazardous reac-

tions

Can react with strong oxidizing agents.

Conditions to avoid : None known.

Incompatible materials : Oxidizing agents Hazardous decomposition : No hazardous de

products

No hazardous decomposition products are known.

#### **SECTION 11. TOXICOLOGICAL INFORMATION**

Information on likely routes of : Inha

exposure

Inhalation Skin contact

Ingestion Eye contact

## **Acute toxicity**

Not classified based on available information.



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**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.



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### 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 - Assess-

ment

Weight of evidence does not support classification as a car-

cinogen



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### 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 - As-

sessment

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



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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 0,38 mg/kg LOAEL 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 symp-

toms, 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

aquatic invertebrates

Toxicity to daphnia and other : EC50 (Daphnia pulex (Water flea)): > 99,5 mg/l

Exposure time: 48 h

Toxicity to fish (Chronic tox-

icity)

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 : NOEC (Daphnia magna (Water flea)): 1 mg/l



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aquatic invertebrates (Chron-

Exposure time: 21 d

ic toxicity) 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 Do not dispose of waste into sewer.

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.



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#### 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 Not applicable

Registry.

Control of precursors and essential chemicals for the

preparation of drugs.

Not applicable

Internal technical data, data from raw material SDSs, OECD

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

**AICS** not determined

DSL not determined

**IECSC** not determined

#### **SECTION 16. OTHER INFORMATION**

Revision Date 30.09.2023 Date format dd.mm.yyyy

### **Further information**

Sources of key data used to compile the Material Safety

Data Sheet

eChem Portal search results and European Chemicals Agency, http://echa.europa.eu/

## Full text of other abbreviations

**ACGIH** USA. ACGIH Threshold Limit Values (TLV) AR OEL Argentina. Occupational Exposure Limits

ACGIH / TWA 8-hour, time-weighted average TLV (Threshold Limit Value) AR OEL / CMP

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 Or-



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ganisation 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; 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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