

Interferon Alfa-2b Liquid Formulation

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 42816-00018 7.2 06.04.2024 Date of first issue: 07.01.2015

Section 1: Identification

Product name Interferon Alfa-2b Liquid Formulation

Manufacturer or supplier's details

Company : MSD

Address 33 Whakatiki Street - Private Bag 908

Upper Hutt - New Zealand

Telephone 0800 800 543

0800 764 766 (0800 POISON) Emergency telephone number: 0800 243 622 (0800

CHEMCALL)

EHSDATASTEWARD@msd.com E-mail address

Recommended use of the chemical and restrictions on use

Recommended use Pharmaceutical Restrictions on use Not applicable

Section 2: Hazard identification

GHS Classification

Reproductive toxicity : Category 1

repeated exposure

Specific target organ toxicity - : 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.

P260 Do not breathe mist or vapours.

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 ad-

vice 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 contact, immediately flush skin with soap and plenty In case of skin contact

of water.

Remove contaminated clothing and shoes.

Get medical attention. Wash clothing before reuse.

Thoroughly clean shoes before reuse. Flush eyes with water as a precaution.

In case of eye contact Get medical attention if irritation develops and persists.

: If swallowed, DO NOT induce vomiting. If swallowed

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

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

Unsuitable extinguishing

media

None known.

Specific hazards during fire-

fighting

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod- :

ucts

No hazardous combustion products are known

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

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 firefighters

In the event of fire, wear self-contained breathing apparatus.

Use personal protective equipment.

Section 6: Accidental release measures

Personal precautions, protective equipment and emer-

gency procedures

Use personal protective equipment.

Follow safe handling advice (see section 7) and personal pro-

tective 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 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 absor-

bent

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 deter-

mine 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.



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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 vapours.

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 as-

sessment

Keep container tightly closed.

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.

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.

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

Section 8: Exposure controls/personal protection

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis	
m-Cresol	108-39-4	WES-TWA (Inhalable Fraction and Vapour)	1 ppm 4.5 mg/m3	NZ OEL	
	Further information: Skin absorption				
		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 ²	Internal	

Engineering measures : Use closed processing systems or containment technologies

to control at source (e.g., glove boxes/isolators) and to pre-

vent leakage of compounds into the workplace.



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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 re-

quired.

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, dis-

posable suits) to avoid exposed skin surfaces.

Use appropriate degowning techniques to remove potentially

contaminated clothing.

Section 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



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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 characteristics

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

products

No hazardous decomposition products are known.



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Section 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: > 2,000 mg/kg

Method: Calculation method

Acute inhalation toxicity : Acute toxicity estimate: > 20 mg/l

Exposure time: 4 h
Test atmosphere: vapour
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 : Acute toxicity estimate: 0.5001 mg/l

Exposure time: 4 h
Test atmosphere: vapour
Method: Expert judgement

Remarks: Based on national or regional regulation.

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



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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.

Chronic toxicity

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



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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

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 develop-

ment

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 develop-

ment

Test Type: Fertility/early embryonic development

Species: Monkey



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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.

Components:

m-Cresol:

Assessment : May cause respiratory irritation.

Remarks : Based on national or regional regulation.

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



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Exposure time 9 d

Remarks No significant adverse effects were reported

Species Monkey LOAEL 0.38 mg/kg Intramuscular Application Route 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

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-

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 :

aquatic invertebrates (Chron-

Exposure time: 21 d

ic toxicity)

Remarks: Based on data from similar materials

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

Persistence and degradability

Components:

m-Cresol:

Biodegradability Result: Readily biodegradable.

Biodegradation: 90 % Exposure time: 28 d

Method: OECD Test Guideline 301D



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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 soilNo 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 han-

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

Section 14: Transport information

International Regulations

UNRTDG

UN number : Not applicable
Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable

Environmentally hazardous : no

IATA-DGR

UN/ID No. : Not applicable
Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable
Packing instruction (cargo : Not applicable

aircraft)

Packing instruction (passen-

Not applicable

ger aircraft)

IMDG-Code

UN number : Not applicable



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Proper shipping name : Not applicable Class : Not applicable Subsidiary risk : Not applicable Packing group : Not applicable Labels : Not applicable EmS Code : Not applicable Marine pollutant : Not applicable

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

Not applicable for product as supplied.

National Regulations

NZS 5433

UN number : Not applicable
Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable
Hazchem Code : Not applicable

Special precautions for user

Not applicable

Section 15: Regulatory information

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

HSNO Approval Number

HSR100425 Pharmaceutical Active Ingredients Group Standard

Tolerable Exposure Limits (TEL)

Not applicable

Environmental Exposure Limits (EEL)

Not applicable

HSW Controls

Certified handler certificate not required.

Tracking hazardous substance not required.

Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.

The components of this product are reported in the following inventories:

AICS : not determined

DSL : not determined

IECSC : not determined

Section 16: Other information



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Further information

Sources of key data used to compile the Safety Data

Sheet

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

Date format : dd.mm.yyyy

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

NZ OEL : New Zealand. Workplace Exposure Standards for Atmospher-

Internal technical data, data from raw material SDSs, OECD

ic Contaminants

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

NZ OEL / WES-TWA : Workplace Exposure Standard - Time Weighted average

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 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 mate-



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rial 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.

NZ / EN