

# Interferon Alfa-2b Solid Formulation

SDS Number: Date of last issue: 2024/04/06 Version **Revision Date:** 11.0 2024/09/28 52733-00022 Date of first issue: 2015/02/02

#### 1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name Interferon Alfa-2b Solid Formulation

Supplier's company name, address and phone number

Company name of supplier MSD

Address Kumagaya, Saitama Prefecture, Xicheng 810 MSD Co., Ltd.

Menuma factory

Telephone 048-588-8411

E-mail address EHSDATASTEWARD@msd.com

Emergency telephone number : +1-908-423-6000

Recommended use of the chemical and restrictions on use

Recommended use **Pharmaceutical** Restrictions on use Not applicable

#### 2. HAZARDS IDENTIFICATION

GHS classification of chemical product

Reproductive toxicity Category 1B

repeated exposure

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

**GHS** label elements

Hazard pictograms

Signal word

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 dust.

P280 Wear protective gloves/ protective clothing/ eye protec-



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tion/ 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.

#### Other hazards which do not result in classification

Important symptoms and outlines of the emergency as-

sumed

Dust contact with the eyes can lead to mechanical irritation. May form explosive dust-air mixture during processing, han-

dling or other means.

#### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)	ENCS No.
Interferon alfa-2b	98530-12-2	>= 1 - < 10	-

## 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 skin contact : In case of contact, immediately flush skin with 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 : If in eyes, rinse well with water.

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.

Dust contact with the eyes can lead to mechanical irritation.

Protection of first-aiders : First Aid responders should pay attention to self-protection,

and use the recommended personal protective equipment



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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 fire-

fighting

Avoid generating dust; fine dust dispersed in air in sufficient

concentrations, and in the presence of an ignition source is a

potential dust explosion hazard.

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod: :

ucts

Carbon oxides

Nitrogen oxides (NOx)

Metal oxides

Phosphorus compounds Oxides of phosphorus Carbon dioxide (CO2)

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.

#### 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 pro-

tective equipment recommendations (see section 8).

Environmental precautions : Avoid release to the environment.

Prevent further leakage or spillage if safe to do so. 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

: Sweep up or vacuum up spillage and collect in suitable con-

tainer for disposal.

Avoid dispersal of dust in the air (i.e., clearing dust surfaces

with compressed air).



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Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. 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 : Static electricity may accumulate and ignite suspended dust

causing an explosion.

Provide adequate precautions, such as electrical grounding

and bonding, or inert atmospheres.

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 dust. 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.

Minimize dust generation and accumulation. Keep container closed when not in use. Keep away from heat and sources of ignition.

Take precautionary measures against static discharges.

Take care to prevent spills, waste and minimize release to the

environment.

Avoidance of contact
Hygiene measures

Oxidizing agents

: 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.

**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:



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Strong oxidizing agents

Packaging material : Unsuitable material: None known.

#### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

# Threshold limit value and permissible exposure limits for each component in the work environment

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Concentration standard / Permissible concentration	Basis
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 pre-

vent 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 : If adequate local exhaust ventilation is not available or expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

Filter type Hand protection Particulates type

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



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contaminated clothing.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state powder

White to light yellow Colour

Odour No data available

Odour Threshold No data available

Melting point/freezing point No data available

Boiling point, initial boiling

point and boiling range

No data available

Flammability (solid, gas) May form explosive dust-air mixture during processing, han-

dling or other means.

Flammability (liquids) No data available

Lower explosion limit and upper explosion limit / flammability limit

Upper explosion limit / Up- : No data available

per flammability limit

Lower explosion limit / Lower flammability limit

: No data available

Flash point Not applicable

Decomposition temperature No data available

pΗ No data available

Evaporation rate Not applicable

Auto-ignition temperature No data available

Viscosity

Viscosity, kinematic Not applicable

Solubility(ies)

Water solubility No data available

Partition coefficient: n-

octanol/water

Not applicable

Vapour pressure Not applicable

Density and / or relative density

Relative density No data available



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Density No data available

Relative vapour density Not applicable

Explosive properties Not explosive

Oxidizing properties The substance or mixture is not classified as oxidizing.

Particle characteristics

Particle size No data available

#### 10. STABILITY AND REACTIVITY

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

Possibility of hazardous reac-

tions

May form explosive dust-air mixture during processing, han-

dling or other means.

Can react with strong oxidizing agents.

Conditions to avoid : Heat, flames and sparks.

Avoid dust formation.

Incompatible materials

Hazardous decomposition

Oxidizing agents

No hazardous decomposition products are known.

products

## 11. TOXICOLOGICAL INFORMATION

Information on likely routes of:

exposure

Inhalation Skin contact

> Ingestion Eye contact

## **Acute toxicity**

Not classified based on available information.

#### Skin corrosion/irritation

Not classified based on available information.

## Components:

#### Interferon alfa-2b:

**Species** Rat

Result Skin irritation

# Serious eye damage/eye irritation

Not classified based on available information.



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#### Components:

#### 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:**

## 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.

## Reproductive toxicity

May damage fertility. May damage the unborn child.

#### **Components:**

#### 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

Developmental Toxicity: LOAEL: 3.8 µg/kg body weight

Result: Embryolethal effects

Reproductive toxicity - As-

sessment

May damage fertility. May damage the unborn child.



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# 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:**

## 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 symp-



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toms, Fever, chills, Fatigue

## 12. ECOLOGICAL INFORMATION

## **Ecotoxicity**

No data available

# Persistence and degradability

No data available

## Bioaccumulative potential

No data available

# Mobility in soil

No data available

#### Hazardous to the ozone layer

Not applicable

#### Other adverse effects

No data available

# 13. DISPOSAL CONSIDERATIONS

# **Disposal methods**

Waste from residues : Dispose of in accordance with local regulations.

Do not dispose of waste into sewer.

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.

#### 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



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aircraft)

Packing instruction (passen: Not applicable

ger aircraft)

**IMDG-Code** 

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

Refer to section 15 for specific national regulation.

## Special precautions for user

Not applicable

# 15. REGULATORY INFORMATION

#### **Related Regulations**

#### Fire Service Law

Not applicable to dangerous materials / designated flammables.

#### **Chemical Substance Control Law**

Not applicable for Specified Chemical Substance, Monitoring Chemical Substance and Priority Assessment Chemical Substance.

## **Industrial Safety and Health Law**

#### Harmful Substances Prohibited from Manufacture

Not applicable

# **Harmful Substances Required Permission for Manufacture**

Not applicable

#### **Substances Prevented From Impairment of Health**

Not applicable

# Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity

Not applicable

# Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity

Not applicable

#### **Substances Subject to be Notified Names**

Not applicable



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#### **Substances Subject to be Indicated Names**

Not applicable

Skin and Eye Damage Substances for PPE Requirements (ISHL MO Art. 594-2)

Not applicable

Carcinogenic Substances (Article 577-2 of the Occupational Health and Safety Regulations)

Not applicable

Ordinance on Prevention of Hazards Due to Specified Chemical Substances

Not applicable

**Ordinance on Prevention of Lead Poisoning** 

Not applicable

Ordinance on Prevention of Tetraalkyl Lead Poisoning

Not applicable

**Ordinance on Prevention of Organic Solvent Poisoning** 

Not applicable

Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)

Not applicable

Poisonous and Deleterious Substances Control Law

Not applicable

Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof

Not applicable

**High Pressure Gas Safety Act** 

Not applicable

**Explosive Control Law** 

Not applicable

**Vessel Safety Law** 

Not regulated as a dangerous good

**Aviation Law** 

Not regulated as a dangerous good

Marine Pollution and Sea Disaster Prevention etc Law

Bulk transportation : Not classified as noxious liquid substance

Pack transportation : Not classified as marine pollutant

**Narcotics and Psychotropics Control Act** 

Narcotic or Psychotropic Raw Material (Export / Import Permission)

Not applicable

Specific Narcotic or Psychotropic Raw Material (Export / Import permission)

Not applicable



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## Waste Disposal and Public Cleansing Law

Industrial waste

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 compile the Safety Data Sheet

Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agenty http://echa.gurana.gu/

cy, http://echa.europa.eu/

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Date format : yyyy/mm/dd

## Full text of other abbreviations

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 - Trans-



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portation 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.

JP / EN