

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Interferon Alfa-2b Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 03.12.2024
4.1	14.04.2025	45284-00023	Date of first issue: 07.01.2015

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name : Interferon Alfa-2b Liquid Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Sub-
stance/Mixture : Pharmaceutical

Recommended restrictions
on use : Not applicable

1.3 Details of the supplier of the safety data sheet

Company : MSD
Kilsheelan
Clonmel Tipperary, IE

Telephone : 353-51-601000

E-mail address of person
responsible for the SDS : EHSDATASTEWARD@msd.com

1.4 Emergency telephone number

+1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Reproductive toxicity, Category 1B

H360FD: May damage fertility. May damage the unborn child.

Specific target organ toxicity - repeated
exposure, Category 2

H373: May cause damage to organs through pro-
longed or repeated exposure.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :



Signal word : Danger

Hazard statements : H360FD May damage fertility. May damage the unborn

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Interferon Alfa-2b Liquid Formulation

Version 4.1 Revision Date: 14.04.2025 SDS Number: 45284-00023 Date of last issue: 03.12.2024
Date of first issue: 07.01.2015

child.
H373 May cause damage to organs through prolonged or repeated exposure.

Precautionary statements :

Prevention:

P201 Obtain special instructions before use.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:

P308 + P313 IF exposed or concerned: Get medical advice/ attention.

Storage:

P405 Store locked up.

Hazardous components which must be listed on the label:

Interferon alfa-2b

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
m-Cresol	108-39-4 203-577-9 604-004-00-9	Acute Tox. 3; H301 Acute Tox. 3; H311 Skin Corr. 1B; H314 Eye Dam. 1; H318 Aquatic Chronic 3; H412 EUH071	>= 0,1 - < 0,25

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Interferon Alfa-2b Liquid Formulation

Version 4.1 Revision Date: 14.04.2025 SDS Number: 45284-00023 Date of last issue: 03.12.2024
Date of first issue: 07.01.2015

		Acute toxicity estimate Acute oral toxicity: 121 mg/kg Acute dermal toxicity: 301 mg/kg	
Interferon alfa-2b	98530-12-2	Skin Irrit. 2; H315 Repr. 1B; H360FD STOT RE 2; H373 (Blood, Bone marrow) specific concentration limit Repr. 1B; H360FD ≥ 0,001 % STOT RE 2; H373 ≥ 0,001 %	≥ 0,001 - < 0,1

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of 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.
- 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).
- 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.

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Interferon Alfa-2b Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 03.12.2024
4.1	14.04.2025	45284-00023	Date of first issue: 07.01.2015

Rinse mouth thoroughly with water.

4.2 Most important symptoms and effects, both acute and delayed

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

4.3 Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media

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

Unsuitable extinguishing media : None known.

5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-fighting : Exposure to combustion products may be a hazard to health.

Hazardous combustion products : No hazardous combustion products are known

5.3 Advice for firefighters

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.

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.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment.
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Interferon Alfa-2b Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 03.12.2024
4.1	14.04.2025	45284-00023	Date of first issue: 07.01.2015

6.2 Environmental precautions

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.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Soak up with inert absorbent material.
For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container.
Clean up remaining materials from spill with suitable absorbent.
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

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

Advice on safe handling : Do not get on skin or clothing.
Do not breathe 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 assessment
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

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Interferon Alfa-2b Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 03.12.2024
4.1	14.04.2025	45284-00023	Date of first issue: 07.01.2015

use of administrative controls.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations.

Advice on common storage : Do not store with the following product types:
Strong oxidizing agents
Self-reactive substances and mixtures
Organic peroxides
Explosives
Gases

7.3 Specific end use(s)

Specific use(s) : No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
m-Cresol	108-39-4	TWA	20 mg/m ³	FOR-2011-12-06-1358
Further information: Chemicals that can be absorbed through the skin.				
Interferon alfa-2b	98530-12-2	TWA	0.2 µg/m ³ (OEB 5)	Internal
		Wipe limit	2 µg/100 cm ²	Internal

Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006

Substance name	End Use	Exposure routes	Potential health effects	Value
m-Cresol	Workers	Inhalation	Long-term systemic effects	3,5 mg/m ³
	Workers	Inhalation	Acute systemic effects	343 mg/m ³
	Workers	Skin contact	Long-term systemic effects	0,5 mg/kg bw/day
	Workers	Skin contact	Acute systemic effects	1,47 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	0,75 mg/m ³
	Consumers	Inhalation	Acute systemic effects	222 mg/m ³
	Consumers	Skin contact	Long-term systemic effects	0,25 mg/kg bw/day
	Consumers	Skin contact	Acute systemic effects	0,74 mg/kg bw/day

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Interferon Alfa-2b Liquid Formulation

Version 4.1 Revision Date: 14.04.2025 SDS Number: 45284-00023 Date of last issue: 03.12.2024
Date of first issue: 07.01.2015

	Consumers	Ingestion	Long-term systemic effects	0,25 mg/kg bw/day
	Consumers	Ingestion	Acute systemic effects	0,74 mg/kg bw/day

Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006

Substance name	Environmental Compartment	Value
m-Cresol	Fresh water	0,1 mg/l
	Marine water	0,01 mg/l
	Intermittent use/release	0,076 mg/l
	Sewage treatment plant	1,14 mg/l
	Fresh water sediment	0,71 mg/kg
	Marine sediment	0,071 mg/kg
	Soil	0,0831 mg/kg

8.2 Exposure controls

Engineering measures

The information below is intended for larger pilot/commercial-scale operations and manufacturing. For smaller scale, clinical, or pharmacy settings, site-specific internal risk assessment practices should be conducted to determine appropriate exposure control measures. The health hazard risks of handling this material are dependent on multiple factors, including but not limited to physical form and quantity handled. If applicable, use process enclosures, local exhaust ventilation (e.g., Biosafety Cabinet, Ventilated Balance Enclosures), or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels as low as reasonably achievable.

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

- Eye/face protection : Wear safety glasses with side shields or goggles.
If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.
Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.
- Hand protection
- Material : Chemical-resistant gloves
- Remarks : Consider double gloving.
- 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.
- Respiratory protection : No personal respiratory protective equipment normally re-

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Interferon Alfa-2b Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 03.12.2024
4.1	14.04.2025	45284-00023	Date of first issue: 07.01.2015

quired.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state	:	liquid
Colour	:	colourless
Odour	:	No data available
Odour Threshold	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flammability (solid, gas)	:	Not applicable
Flammability (liquids)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Flash point	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
pH	:	6,5 - 8
Viscosity		
Viscosity, kinematic	:	No data available
Solubility(ies)		
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	Not applicable
Vapour pressure	:	No data available
Relative density	:	No data available

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Interferon Alfa-2b Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 03.12.2024
4.1	14.04.2025	45284-00023	Date of first issue: 07.01.2015

Density : No data available

Relative vapour density : No data available

Particle characteristics
Particle size : Not applicable

9.2 Other information

Explosives : Not explosive

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

Evaporation rate : No data available

Molecular weight : Not applicable

SECTION 10: Stability and reactivity

10.1 Reactivity

Not classified as a reactivity hazard.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : Can react with strong oxidizing agents.

10.4 Conditions to avoid

Conditions to avoid : None known.

10.5 Incompatible materials

Materials to avoid : Oxidizing agents

10.6 Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Information on likely routes of exposure :
Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity

Not classified based on available information.

Product:

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Interferon Alfa-2b Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 03.12.2024
4.1	14.04.2025	45284-00023	Date of first issue: 07.01.2015

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 sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Interferon Alfa-2b Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 03.12.2024
4.1	14.04.2025	45284-00023	Date of first issue: 07.01.2015

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-	:	Weight of evidence does not support classification as a car-

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Interferon Alfa-2b Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 03.12.2024
4.1	14.04.2025	45284-00023	Date of first issue: 07.01.2015

ment

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 development : Test Type: Prenatal development toxicity study (teratogenicity)
Species: Rat
Application Route: Ingestion
Result: negative

Interferon alfa-2b:

Effects on fertility : Test Type: Fertility/early embryonic development
Species: Monkey
Fertility: LOAEL: 3,8 µg/kg
Result: menstrual irregularities
Remarks: Abortion

Effects on foetal development : Test Type: Fertility/early embryonic development
Species: Monkey
Developmental Toxicity: LOAEL: 3,8 µg/kg body weight
Result: Embryo-lethal effects

Reproductive toxicity - Assessment : May damage fertility. May damage the unborn child.

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

May cause damage to organs through prolonged or repeated exposure.

Components:

Interferon alfa-2b:

Target Organs : Blood, Bone marrow
Assessment : May cause damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

m-Cresol:

Species : Rat
NOAEL : 150 mg/kg

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Interferon Alfa-2b Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 03.12.2024
4.1	14.04.2025	45284-00023	Date of first issue: 07.01.2015

Application Route : Ingestion
Exposure time : 13 Weeks
Method : OECD Test Guideline 408

Interferon alfa-2b:

Species : Monkey
NOAEL : 0,095 mg/kg
Application Route : Intramuscular
Exposure time : 1 Months
Remarks : No significant adverse effects were reported

Species : Rat
NOAEL : 0,38 mg/kg
Application Route : Subcutaneous
Exposure time : 3 Months
Remarks : No significant adverse effects were reported

Species : Mouse
NOAEL : 0,076 mg/kg
Application Route : Intraperitoneal
Exposure time : 9 d
Remarks : No significant adverse effects were reported

Species : Monkey
LOAEL : 0,38 mg/kg
Application Route : Intramuscular
Exposure time : 3 Months
Target Organs : Blood, Bone marrow
Remarks : Significant toxicity observed in testing

Aspiration toxicity

Not classified based on available information.

11.2 Information on other hazards

Endocrine disrupting properties

Not classified based on available information.

Product:

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Experience with human exposure

Components:

Interferon alfa-2b:

Skin contact : Symptoms: The most common side effects are:, flu-like symptoms, Fever, chills, Fatigue

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Interferon Alfa-2b Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 03.12.2024
4.1	14.04.2025	45284-00023	Date of first issue: 07.01.2015

SECTION 12: Ecological information

12.1 Toxicity

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 toxicity)	:	NOEC: 1,35 mg/l Exposure time: 32 d Species: Pimephales promelas (fathead minnow) Remarks: Based on data from similar materials
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC: 1 mg/l Exposure time: 21 d Species: Daphnia magna (Water flea) Remarks: Based on data from similar materials

12.2 Persistence and degradability

Components:

m-Cresol:

Biodegradability	:	Result: Readily biodegradable. Biodegradation: 90 % Exposure time: 28 d Method: OECD Test Guideline 301D
------------------	---	---

12.3 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

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

Product:

Assessment	:	This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or
------------	---	---

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Interferon Alfa-2b Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 03.12.2024
4.1	14.04.2025	45284-00023	Date of first issue: 07.01.2015

very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Endocrine disrupting properties

Product:

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 Other adverse effects

No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product	: Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities. Do not dispose of waste into sewer.
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

14.1 UN number or ID number

ADN	: Not regulated as a dangerous good
ADR	: Not regulated as a dangerous good
RID	: Not regulated as a dangerous good
IMDG	: Not regulated as a dangerous good
IATA	: Not regulated as a dangerous good

14.2 UN proper shipping name

ADN	: Not regulated as a dangerous good
ADR	: Not regulated as a dangerous good
RID	: Not regulated as a dangerous good
IMDG	: Not regulated as a dangerous good
IATA	: Not regulated as a dangerous good

14.3 Transport hazard class(es)

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Interferon Alfa-2b Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 03.12.2024
4.1	14.04.2025	45284-00023	Date of first issue: 07.01.2015

ADN	: Not regulated as a dangerous good
ADR	: Not regulated as a dangerous good
RID	: Not regulated as a dangerous good
IMDG	: Not regulated as a dangerous good
IATA	: Not regulated as a dangerous good

14.4 Packing group

ADN	: Not regulated as a dangerous good
ADR	: Not regulated as a dangerous good
RID	: Not regulated as a dangerous good
IMDG	: Not regulated as a dangerous good
IATA (Cargo)	: Not regulated as a dangerous good
IATA (Passenger)	: Not regulated as a dangerous good

14.5 Environmental hazards

Not regulated as a dangerous good

14.6 Special precautions for user

Not applicable

14.7 Maritime transport in bulk according to IMO instruments

Remarks	: Not applicable for product as supplied.
---------	---

SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII)	: Conditions of restriction for the following entries should be considered: Number on list 3
--	---

Number on list 75: If you intend to use this product as tattoo ink, please contact your vendor.

Substance(s) or mixture(s) are listed here according to their appearance in the regulation, irrespective of their use/purpose or the conditions of the restriction. Please refer to the conditions in corresponding Regulation to determine whether an entry is applicable to the placing on the market or not.

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59).	: Not applicable
---	------------------

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Interferon Alfa-2b Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 03.12.2024
4.1	14.04.2025	45284-00023	Date of first issue: 07.01.2015

REACH - List of substances subject to authorisation : Not applicable
(Annex XIV)
Regulation (EU) No 2024/590 on substances that deplete the ozone layer : Not applicable
Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable
Regulation (EU) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Not applicable
Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.
Not applicable

Other regulations:

Note the Working Environment Act § 4-1 and § 4-2 on requirements for the employer to protect pregnant employees against discomfort and injury as a result of the work situation and the working environment.

Note the regulation on organization, leadership and participation, chapter 12 on the work of children and young people.

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

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

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

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

Full text of H-Statements

H301 : Toxic if swallowed.
H311 : Toxic in contact with skin.
H314 : Causes severe skin burns and eye damage.
H315 : Causes skin irritation.
H318 : Causes serious eye damage.
H360FD : May damage fertility. May damage the unborn child.
H373 : May cause damage to organs through prolonged or repeated exposure.
H412 : Harmful to aquatic life with long lasting effects.
EUH071 : Corrosive to the respiratory tract.

Full text of other abbreviations

Acute Tox. : Acute toxicity
Aquatic Chronic : Long-term (chronic) aquatic hazard

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Interferon Alfa-2b Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 03.12.2024
4.1	14.04.2025	45284-00023	Date of first issue: 07.01.2015

Eye Dam.	: Serious eye damage
Repr.	: Reproductive toxicity
Skin Corr.	: Skin corrosion
Skin Irrit.	: Skin irritation
STOT RE	: Specific target organ toxicity - repeated exposure
FOR-2011-12-06-1358	: Norway. Occupational Exposure limits
FOR-2011-12-06-1358 / TWA	: Long term exposure limit

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; 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

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 Agency, <http://echa.europa.eu/>

Classification of the mixture:

Repr. 1B	H360FD
STOT RE 2	H373

Classification procedure:

Calculation method
Calculation method

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Interferon Alfa-2b Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 03.12.2024
4.1	14.04.2025	45284-00023	Date of first issue: 07.01.2015

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.

NO / EN