

against

Interferon Alfa-2b Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
5.0	28.09.2024	2436394-00015	Date of first issue: 09.02.2018

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

: EHSDATASTEWARD@msd.com

1.1 Product identifier		
Trade name	:	Interferon Alfa-2b Solid Formulation
1.2 Relevant identified uses of	the s	ubstance or mixture and uses advised a
Use of the Sub- stance/Mixture	:	Pharmaceutical
Recommended restrictions on use	:	Not applicable
1.3 Details of the supplier of th	e saf	ety data sheet
Company	:	MSD Kilsheelan . Clonmel Tipperary, IE
Telephone	:	353-51-601000

1.4 Emergency telephone number

E-mail address of person

responsible for the SDS

National Poison Control Center (UZEM): 114 Emergency: 1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification T.R. SEA No 28848 and subsequent amendments

Reproductive toxicity, Category 1B

Specific target organ toxicity - repeated exposure, Category 2

2.2 Label elements

H360FD: May damage fertility. May damage the unborn child. H373: May cause damage to organs through prolonged or repeated exposure.

Labelling T.R. SEA No 28848 and subsequent amendments

Hazard pictograms	:		
Signal word	:	Danger	
Hazard statements	:	H360FD	May damage fe

May damage fertility. May damage the unborn

Prepared in accordance with the provisions of KKDIK Annex-2 Regulation, 23.06.2017, No: 30105



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		child. H373 May caus repeated exposur	e damage to organs through prolonged or e.
Preca	utionary statements	Prevention:	
		P260 Do not br	ecial instructions before use. eathe dust. tective gloves/ protective clothing/ eye protec- on.
		Response: P308 + P313 IF attention.	exposed or concerned: Get medical advice/
		Storage: P405 Store lock	ked up.

Hazardous components which must be listed on the label: Interferon alfa-2b

2.3 Other hazards

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

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Chemical name	CAS-No. EC-No. Index-No. KKDIK Registra- tion No.	SEA Classification	Concentration (% w/w)
Interferon alfa-2b	98530-12-2	Skin Irrit. 2; H315 Repr. 1B; H360FD STOT RE 2; H373 (Blood, Bone mar- row) specific concentra- tion limit Repr. 1B; H360FD >= 0,001 % STOT RE 2; H373 >= 0,001 %	>= 1 - < 10

For explanation of abbreviations see section 16.



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SECTION 4: First aid measures

4.1 Description of first aid measu	4.1 Description of 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.		
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 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.		
4.2 Most important symptoms an	nd e	effects, both acute and delayed		
Risks	:	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.		
4.3 Indication of any immediate n	ne	dical 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.



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	-	hazards arising from	the		
	Specific fighting	c hazards during fire-	:	concentrations, a potential dust exp	dust; fine dust dispersed in air in sufficient nd in the presence of an ignition source is a losion hazard. pustion products may be a hazard to health.
	Hazard ucts	lous combustion prod-	:	Carbon oxides Nitrogen oxides (I Metal oxides Phosphorus com Oxides of phosph Carbon dioxide (C	orus
5.3 A	Advice	for firefighters			
	Specia for firef	l protective equipment ighters	:		e, wear self-contained breathing apparatus. tective equipment.
	Specifi ods	c extinguishing meth-	:	cumstances and tuse water spray to	measures that are appropriate to local cir- the surrounding environment. to cool unopened containers. ged containers from fire area if it is safe to do

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 pro- tective equipment recommendations (see section 8).
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6.2 Environmental precautions

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.
		cannot be contained.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up		tainer for disposal. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Dust deposits should not be allowed to accumulate on surfac- es, as these may form an explosive mixture if they are re- leased into the atmosphere in sufficient concentration. Local or national regulations may apply to releases and dis- posal 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.
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			d 15 of this SDS provide information regarding 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	:	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.
	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 contami- nated 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.
7.2	Conditions for safe storage, in	ncl	uding 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:

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



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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	
Dust	15 mg/m3 Value type (Form of exposure): ZOAD/TWA (Total dust) Basis: TR OEL DU Further information: Allowable occupational exposure limit values of mineral dusts
	5 mg/m3 Value type (Form of exposure): ZOAD/TWA (Respirable part) Basis: TR OEL DU Further information: Allowable occupational exposure limit values of mineral dusts

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Interferon alfa-2b	98530-12-2	TWA	0.2 μg/m3 (OEB 5)	Internal
		Wipe limit	2 µg/100 cm ²	Internal

Derived No Effect Level (DNEL)

Substance name	End Use	Exposure routes	Potential health ef- fects	Value
Disodium hy- drogenorthophos- phate	Workers	Inhalation	Long-term systemic effects	4,07 mg/m3
	Consumers	Inhalation	Long-term systemic effects	3,04 mg/m3

Predicted No Effect Concentration (PNEC)

Substance name	Environmental Compartment	Value
Disodium hydrogenorthophos-	Fresh water	0,05 mg/l
phate		
	Marine water	0,005 mg/l
	Intermittent use/release	0,5 mg/l
	Sewage treatment plant	50 mg/l

8.2 Exposure controls

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.



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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 equipm	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 Skin and body protection	:	Consider double gloving. 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	:	If adequate local exhaust ventilation is not available or expo- sure assessment demonstrates exposures outside the rec- ommended guidelines, use respiratory protection. Equipment should conform to TS EN 143				
Filter type	:	Particulates type (P)				

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance Colour Odour Odour Threshold	:	powder White to light yellow No data available No data available
рН	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	Not applicable
Evaporation rate	:	Not applicable
Flammability (solid, gas)	:	May form explosive dust-air mixture during processing, han- dling or other means.
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower	:	No data available

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flamn	nability limit			
Vapo	Vapour pressure		Not applicable	
Relat	ive vapour density	:	Not applicable	
Relat	ive density	:	No data available	e
Dens	ity	:	No data available	e
W Partit octan Auto- Deco Visco Visco	pility(ies) ater solubility ion coefficient: n- ol/water ignition temperature mposition temperature sity scosity, kinematic sive properties zing properties	::	No data available Not applicable No data available No data available Not applicable Not explosive The substance of	e
	information mability (liquids)	:	No data availabl	e
Partic	sle size	:	No data availabl	e

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 May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents. 10.4 Conditions to avoid Heat, flames and sparks. Avoid dust formation. 10.5 Incompatible materials Oxidizing agents

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10.6 Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

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

Acute toxicity

Not classified based on available information.

Skin corrosion/irritation

Not classified based on available information.

Components:

Interferon alfa-2b:

Species Result	: Ra	t
Result	: Sk	in irritation

Serious eye damage/eye irritation

Not classified based on available information.

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

Remarks

Species NOAEL

Application Route

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			Species: Mouse Result: negative Remarks: Based	on data from similar materials
	inogenicity lassified based on avai	lablo	information	
	oductive toxicity	lable	information.	
-	damage fertility. May da	amag	e the unborn child	l.
Com	ponents:			
Inter	feron alfa-2b:			
Effec	ts on fertility	:	Test Type: Fertili Species: Monkey Fertility: LOAEL: Result: menstrua Remarks: Abortic	3,8 μg/kg al irregularities
Effec ment	ts on foetal develop-	:	Species: Monkey	oxicity: LOAEL: 3,8 μg/kg body weight
Repro sessr	oductive toxicity - As- nent	:	May damage fert	tility. May damage the unborn child.
	F - single exposure lassified based on avai	lable	information.	
STO	Г - repeated exposure			
May	cause damage to orgar	ns thr	ough prolonged or	repeated exposure.
Com	ponents:			
Inter	feron alfa-2b:			
	et Organs ssment	:	Blood, Bone mar May cause dama exposure.	row age to organs through prolonged or repeated
Repe	ated dose toxicity			
<u>Com</u>	ponents:			
Inter	feron alfa-2b:			
Expo		:	Monkey 0,095 mg/kg Intramuscular 1 Months	verse effects were reported

0,38 mg/kg

:

:

:

:

Rat

No significant adverse effects were reported

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Rema	es	: Mouse	dverse effects were reported
Speci	EL	: 0,076 mg/kg	
NOAE	cation Route	: Intraperitoneal	
Applio	sure time	: 9 d	
Expos	L cation Route sure time of Organs	 Monkey 0,38 mg/kg Intramuscular 3 Months Blood, Bone marrow Significant toxicity observed in testing 	

Aspiration toxicity

Not classified based on available information.

:

:

Experience with human exposure

Components:

Interferon alfa-2b:

Skin contact

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

SECTION 12: Ecological information

12.1 Toxicity

No data available

12.2 Persistence and degradability

No data available

12.3 Bioaccumulative potential

No data available

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

Not relevant

12.6 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



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Conta	minated packaging	Waste codes s discussion with Do not dispose Empty containe dling site for re	t specific, but application specific. hould be assigned by the user, preferably in the waste disposal authorities. of waste into sewer. ers should be taken to an approved waste han- cycling or disposal. e specified: Dispose of as unused product.

SECTION 14: Transport information

14.1 UN 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
ΙΑΤΑ	:	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
ΙΑΤΑ	:	Not regulated as a dangerous good
14.3 Transport hazard class(es)		
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
ΙΑΤΑ	:	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		

14.5 Environmental hazards

Not regulated as a dangerous good



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14.6 Special precautions for user

Not applicable

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

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

KKDIK (30105 (Bis)) - Restrictions on the manufacture,	:	Not applicable
placing on the market and use of certain dangerous		
substances, mixtures and articles (Annex 17)		
Regulation on Persistent Organic Pollutants (Number	:	Not applicable
30595 and subsequent amendments published)		
Regulation on prevention of major industrial accidents. Re	g r	umber 30702
Not applicable		

Other regulations:

T.R. Regulation on Classification, Labeling and Packaging of Substances and Mixtures, dated December 11, 2013 and numbered 28848 from the Ministry of Environment and Urbanization and the subsequent amendments published. Regulation on Import and Export of Certain Hazardous : Not applicable Chemicals, No. 32087, 2023

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. The SDS has been prepared by: Name: Gökhan Ardıç; Con- tact email: sds@chemleg.com; Telephone number: +90 216 706 1307; Certificate Number: Lonca KDU 34 / 2020.08; Cer- tificate Date: 22 September 2020; Valid Until: 22 September 2025
Full text of H-Statements	

H315 : Causes skin irritation.



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H373 : May cause da		, ,	rtility. May damage the unborn child. hage to organs through prolonged or repeated

The Turkish SDS has been prepared according to the Regulation on Safety Data Sheets for Hazardous Substances and Mixtures No. 29204.

Full text of other abbreviations

Repr.	:	Reproductive toxicity	
Skin Irrit.	:	Skin irritation	
STOT RE	:	Specific target organ toxicity - repeated exposure	
TR OEL DU	:	Türkiye. Regulation on Dust Control. Occupational Dust Expo-	
		sure Limit Values (Annex 1)	
TR OEL DU / ZOAD/TWA	:	Time Weighted Average Value	

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/



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Classification of the mixture:			Classification procedure:
Repr.	1B	H360FD	Calculation method
STOT	RE 2	H373	Calculation method

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The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

TR / EN