according to GB/T 16483 and GB/T 17519



Interferon Alfa-2b Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2024/04/06
3.0	2024/09/28	42806-00019	Date of first issue: 2015/01/07

1. PRODUCT AND COMPANY IDENTIFICATION

Product name	:	Interferon Alfa-2b Liquid Formulation		
Manufacturer or supplier's de	eta	ils		
Company	:	MSD		
Address	:	199 Wenhai North Road HEDA, Hangzhou - Zhejiang Province - CHINA 310018		
Telephone	:	908-740-4000		
Emergency telephone number	:	86-571-87268110		
E-mail address	:	EHSDATASTEWARD@msd.com		
Recommended use of the chemical and restrictions on use				
Recommended use Restrictions on use	:	Pharmaceutical Not applicable		

2. HAZARDS IDENTIFICATION

Emergency Overview

Appearance Colour Odour	:	liquid colourless No data available
May damage fertility. May dama longed or repeated exposure.	age	e the unborn child. May cause damage to organs through pro-
GHS Classification		
Reproductive toxicity	:	Category 1B
Specific target organ toxicity - repeated exposure	:	Category 2
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 through prolonged or re-

according to GB/T 16483 and GB/T 17519



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Preca	utionary statements	P202 Do not ha and understood P260 Do not bre	ecial instructions before use. ndle until all safety precautions have been read eathe mist or vapours. tective gloves/ protective clothing/ eye protec-
		Response:	exposed or concerned: Get medical advice/
		Storage: P405 Store lock	xed up.
		Disposal: P501 Dispose o disposal plant.	of contents/ container to an approved waste

Physical and chemical hazards

Not classified based on available information.

Health hazards

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

Environmental hazards

Not classified based on available information.

Other hazards which do not result in classification

None known.

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

4. FIRST AID MEASURES

General advice	In the case of accident or if you fee vice immediately. When symptoms persist or in all ca advice.	
If inhaled	If inhaled, remove to fresh air.	

according to GB/T 16483 and GB/T 17519



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	In case	of skin contact	:	of water. Remove contamir Get medical atten Wash clothing be	nated clothing and shoes. tion. fore reuse.	
	In case	of eye contact	:	Flush eyes with w	shoes before reuse. rater as a precaution.	
	If swallowed		:	Get medical attention if irritation develops and persists. If swallowed, DO NOT induce vomiting. Get medical attention.		
	and effe	nportant symptoms ects, both acute and d ion of first-aiders	:	May cause damage exposure. First Aid responder and use the record	lity. May damage the unborn child. ge to organs through prolonged or repeated ers should pay attention to self-protection, nmended personal protective equipment	
	Notes to physician		:	when the potential for exposure exists (see section 8). Treat symptomatically and supportively.		
5. FI	5. FIREFIGHTING MEASURES					
	Suitable	e extinguishing media	:	Water spray Alcohol-resistant Carbon dioxide (C Dry chemical		
	Unsuita media	able extinguishing	:	None known.		
	Specific fighting	c hazards during fire-	:	Exposure to comb	pustion products may be a hazard to health.	
	Hazard ucts	ous combustion prod-	- : No hazardous combustion products are known		mbustion products are known	
	Specific ods	c extinguishing meth-	:	cumstances and t Use water spray t	measures that are appropriate to local cir- he surrounding environment. o cool unopened containers. ged containers from fire area if it is safe to do	
	Special for firef	l protective equipment ighters	:		e, wear self-contained breathing apparatus. tective equipment.	

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protec- :	Use personal protective equipment.
tive equipment and emer-	Follow safe handling advice (see section 7) and personal pro-
gency procedures	tective equipment recommendations (see section 8).

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Envi	ronmental precautions	:	Prevent spreading barriers). Retain and dispos	akage or spillage if safe to do so. g over a wide area (e.g. by containment or oil se of contaminated wash water. should be advised if significant spillages
Methods and materials for containment and cleaning up		:	For large spills, pu ment to keep mat be pumped, store Clean up remainin bent. Local or national up posal of this mate employed in the of mine which regula Sections 13 and 1	t absorbent material. rovide dyking or other appropriate contain- erial from spreading. If dyked material can recovered material in appropriate container. In materials from spill with suitable absor- regulations may apply to releases and dis- rial, as well as those materials and items leanup of releases. You will need to deter- ations are applicable. 5 of this SDS provide information regarding tional requirements.

7. HANDLING AND STORAGE

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.

Advice on safe handling Avoidance of contact Storage	:	ventilation. 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. Oxidizing agents
•		Kaan in properly loballed containers
Conditions for safe storage Materials to avoid	:	Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations. Do not store with the following product types: Strong oxidizing agents

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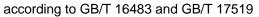
Packaging material : Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis
m-Cresol	108-39-4	PC-TWA	10 mg/m3	CN OEL
	Further informa	ation: Skin		
	TWA (Inhal- 20 mg/m3 able 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. 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 tech- nology designed to prevent leakage of compounds into the workplace.
Personal protective equipm	ent	
Respiratory protection	:	No personal respiratory protective equipment normally re- quired.
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.
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.
Hand protection		
Material	:	Chemical-resistant gloves
Remarks	:	Consider double gloving.
		E / 1E





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Hygien	ie measures	eye flushing syste ing place. When using do n Wash contaminat The effective ope engineering conta appropriate dego	emical is likely during typical use, provide ems and safety showers close to the work- ot eat, drink or smoke. ted clothing before re-use. eration of a facility should include review of rols, proper personal protective equipment, wning and decontamination procedures, e monitoring, medical surveillance and the tive controls.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	liquid
Colour	:	colourless
Odour	:	No data available
Odour Threshold	:	No data available
рН	:	6.5 - 8
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	No data available
Evaporation rate	:	No data available
Flammability (solid, gas)	:	Not applicable
Flammability (liquids)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
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

according to GB/T 16483 and GB/T 17519



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	ion coefficient: n-	: Not applicabl	e
	ol/water ignition temperature	: No data avail	able
Deco	mposition temperature	: No data avail	able
Visco Vi	osity scosity, kinematic	: No data avail	able
Explo	osive properties	: Not explosive)
Oxidi	zing properties	: The substand	ce or mixture is not classified as oxidizing.
Mole	cular weight	: Not applicabl	e
	cle characteristics cle size	: Not applicabl	e

10. STABILITY AND REACTIVITY

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reac-	:	Can react with strong oxidizing agents.
tions		
Conditions to avoid	:	None known.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition	:	No hazardous decomposition products are known.
products		

11. TOXICOLOGICAL INFORMATION

: Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity

Not classified based on available information.

Product:

Acute oral toxicity	:	Acute toxicity estimate: > 5,000 mg/kg Method: Calculation method
Acute dermal toxicity	:	Acute toxicity estimate: > 5,000 mg/kg Method: Calculation method

Components:

m-Cresol:

according to GB/T 16483 and GB/T 17519



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ersion)	Revision Date: 2024/09/28	SDS Number: 42806-00019	Date of last issue: 2024/04/06 Date of first issue: 2015/01/07
Acute	e oral toxicity	: LD50 (Rat): 12 Remarks: Bas	21 mg/kg ed on data from similar materials
Acute	e inhalation toxicity	: Assessment: (Corrosive to the respiratory tract.
Acute	e dermal toxicity	: LD50 (Rabbit) Remarks: Bas	: 301 mg/kg ed on data from similar materials
Skin	corrosion/irritation		
Not c	lassified based on ava	ailable information.	
<u>Com</u>	ponents:		
m-Cr	esol:		
Speci Resu		: Rabbit	r 2 minutes to 1 hour of exposure
Resu	ii.	. Conosive alle	r 3 minutes to 1 hour of exposure
Interf	feron alfa-2b:		
Speci Resu		: Rat : Skin irritation	
	ous eye damage/eye		
Not c	lassified based on ava	ailable information.	
<u>Com</u>	ponents:		
m-Cr			
Speci	ies	: Rabbit	acts on the eve
Resu	IL		ects on the eye
Interf	ieron alfa-2b:		
Speci Rema		: Rabbit	
Rema		: slight irritation	
Resp	iratory or skin sensi	tisation	
noop	•		
-	sensitisation		
Skin	sensitisation lassified based on ava	ailable information.	
Skin Not c			
Skin Not c Resp	lassified based on ava		
Skin Not c Resp Not c Germ	lassified based on ava	ailable information.	
Skin Not c Resp Not c Germ Not c	lassified based on ava iratory sensitisation lassified based on avain cell mutagenicity	ailable information.	
Skin Not c Resp Not c Germ Not c	lassified based on avainatory sensitisation lassified based on avaination cell mutagenicity lassified based on avaination	ailable information.	

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			Method: OEC Result: positiv	D Test Guideline 473 /e
				acterial reverse mutation assay (AMES) D Test Guideline 471 ive
Geno	toxicity in vivo	:	cytogenetic te Species: Mou Application R	oute: Ingestion D Test Guideline 475
Interf	eron alfa-2b:			
Geno	toxicity in vitro	:	Test Type: Cl Result: negat	nromosome aberration test in vitro ive
			Test Type: Ba Result: negat	acterial reverse mutation assay (AMES) ive
Geno	toxicity in vivo	:	Species: Mou Result: negat	
II Carci	nogenicity			
	lassified based on avai	ilable	information.	
<u>Com</u>	ponents:			
m-Cro Speci Applio Expos Resu Resu	es cation Route sure time It		Mouse, males Ingestion 105 weeks equivocal Based on dat	s a from similar materials
Speci Applic Expos Resu Resu	cation Route sure time It		Mouse, femal Ingestion 106 - 107 we positive Based on dat	
	nogenicity - Assess-	:		dence does not support classification as a car-

Reproductive toxicity

May damage fertility. May damage the unborn child.

according to GB/T 16483 and GB/T 17519



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ersion)	Revision Date: 2024/09/28	SDS Number: 42806-00019	Date of last issue: 2024/04/06 Date of first issue: 2015/01/07
Comp	oonents:		
m-Cre			
Effect	s on fertility	: Test Type: Two Species: Rat Application Ro Result: negativ	
Effect ment	s on foetal develop-	: Test Type: Pre Species: Rat Application Ro Result: negativ	
Interf	eron alfa-2b:		
Effect	s on fertility	Species: Monk Fertility: LOAE	L: 3.8 μg/kg ual irregularities
Effect: ment	s on foetal develop-	Species: Monk	I Toxicity: LOAEL: 3.8 μg/kg body weight
Repro sessm	ductive toxicity - As- nent	: May damage f	ertility. May damage the unborn child.

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

according to GB/T 16483 and GB/T 17519



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Interferon alfa-2b:

Species NOAEL Application Route Exposure time Remarks	 Monkey 0.095 mg/kg Intramuscular 1 Months No significant adverse effects were reported
	 Rat 0.38 mg/kg Subcutaneous 3 Months No significant adverse effects were reported
Species NOAEL Application Route Exposure time Remarks	 Mouse 0.076 mg/kg Intraperitoneal 9 d No significant adverse effects were reported
Species LOAEL Application Route Exposure time Target Organs Remarks	 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

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

according to GB/T 16483 and GB/T 17519



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ersion 0	Revision Date: 2024/09/28		S Number: 806-00019	Date of last issue: 2024/04/06 Date of first issue: 2015/01/07
Toxicity)	y to fish (Chronic tox-	:	Exposure time:	ales promelas (fathead minnow)): 1.35 mg 32 d d on data from similar materials
	y to daphnia and other invertebrates (Chron- ity)	:	Exposure time:	a magna (Water flea)): 1 mg/l 21 d d on data from similar materials
Persis	tence and degradabili	ity		
Comp	onents:			
m-Cre	sol:			
Biodeg	radability	:	Result: Readily Biodegradation: Exposure time: Method: OECD	90 %
Bioaco	cumulative potential			
Comp	onents:			
m-Cre	sol:			
Bioacc	umulation	:		cus idus (Golden orfe) n factor (BCF): 17 - 20
Partitio octano	n coefficient: n- I/water	:	log Pow: 1.96	
	t y in soil a available			
	adverse effects a available			

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.	

14. TRANSPORT INFORMATION

International Regulations

UNRTDG

according to GB/T 16483 and GB/T 17519



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Pro Cla Su Pa La En UN Pro	I number oper shipping name ass bsidiary risk cking group bels vironmentally hazardous FA-DGR I/ID No. oper shipping name	 Not applicable Not applicable Not applicable Not applicable Not applicable no Not applicable Not applicable	
Su Pa La Pa	bsidiary risk cking group bels cking instruction (cargo craft)	Not applicable Not applicable Not applicable Not applicable Not applicable	
ge UN Pro Cla Su Pa La En	cking instruction (passen- r aircraft) DG-Code I number oper shipping name ass bsidiary risk cking group bels nS Code arine pollutant	 Not applicable Not applicable Not applicable Not applicable Not applicable Not applicable Not applicable Not applicable no	

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

Not applicable for product as supplied.

National Regulations

GB 6944/12268

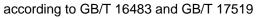
UN number	:	Not applicable
Proper shipping name	:	Not applicable
Class	:	Not applicable
Subsidiary risk	:	Not applicable
Packing group	:	Not applicable
Labels	:	Not applicable
Marine pollutant	:	no

Special precautions for user

Not applicable

15. REGULATORY INFORMATION

National regulatory information Law on the Prevention and Control of Occupational Diseases Regulations on Safety Management of Hazardous Chemicals





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Cat	alogue of Hazardous Che	micals	: This product is not listed in the cata- logue of hazardous chemicals, but it meets the definition of hazardous chemicals and its principles of de- termination.
lder 182	ntification of Major Hazard 18)	Installations for Ha	zardous Chemicals (GB : Not listed
Haz SAV	ardous Chemicals for Pric	prity Management u	nder : Not listed
	Julations on Labour Pro t alogue of Highly Toxic Ch	•	ces where Toxic Substances are Used : Not listed
and Chi	ulation of Environmenta Export of Toxic Chemic na Severely Restricted To Export	als	the First Import of Chemicals and the Import
-	Julation on the Administ alogue and Classification		
	estructure does not contain		micals prohibited for inland river transport.
	components of this pro	, ,	in the following inventories:
DSI	-	: not determined	l
IEC	SC	: not determined	I
16. OTH	ER INFORMATION		
Rev	ision Date	: 2024/09/28	
Fur	ther information		
	rces of key data used to pile the Safety Data et		cal data, data from raw material SDSs, OECD search results and European Chemicals Agen- europa.eu/
	ns where changes have be ument by two vertical lines		vious version are highlighted in the body of this
Date	e format	: yyyy/mm/dd	
Full	text of other abbreviation	ons	
		14 / 15	5



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ACGIH CN OEL	 USA. ACGIH Threshold Limit Values (TLV) Occupational exposure limits for hazardous agents in the workplace - Chemical hazardous agents. 	
ACGIH / TWA CN OEL / PC-TWA	 8-hour, time-weighted average Permissible concentration - 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

Disclaimer

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.

CN/EN