according to the Globally Harmonized System



Interferon Alfa-2b Solid Formulation

Version	Revision Date: 28.09.2024	SDS Number:	Date of last issue: 30.09.2023
7.0		53079-00020	Date of first issue: 02.02.2015

1. PRODUCT AND COMPANY IDENTIFICATION

Product name	:	Interferon Alfa-2b Solid Formulation
Manufacturer or supplier's de	eta	ils
Company	:	MSD
Address	:	Briahnager - Off Pune Nagar Road Wagholi - Pune - India 412 207
Telephone	:	+1-908-740-4000
Emergency telephone number	:	+1-908-423-6000
E-mail address	:	EHSDATASTEWARD@msd.com
Recommended use of the ch	em	ical and restrictions on use
Recommended use Restrictions on use	:	Pharmaceutical Not applicable

2. HAZARDS IDENTIFICATION

Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

Classification

Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

GHS Classification		
Skin corrosion/irritation	:	Category 3
Reproductive toxicity	:	Category 1B
Specific target organ toxicity - repeated exposure	:	Category 2 (Blood, Bone marrow)
GHS label elements		
Hazard pictograms	:	
Signal word	:	Danger
Hazard statements	:	H316 Causes mild skin irritation. H360FD May damage fertility. May damage the unborn child. H373 May cause damage to organs (Blood, Bone marrow) through prolonged or repeated exposure.

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Droop	utionan (atatamanta		
Preca	autionary statements	Prevention:	
		P260 Do not l	
		P280 Wear pl tion/ face prot	rotective gloves/ protective clothing/ eye protec- ection.
		Response:	
			sed or concerned, get medical advice. If skin irritation occurs: Get medical help.
		Storage:	
		P405 Store lo	cked up.
		Disposal:	
		P501 Dispose disposal plant	e of contents/ container to an approved waste
Other	r hazards which do n	ot result in classific	ation
••	contact with the eyes		
			ssing, handling or other means.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance /	Mixture	:	Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Glycine	56-40-6	>= 70 - < 90
Interferon alfa-2b	98530-12-2	>= 1 - < 5

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	:	Causes mild skin irritation. 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.

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	ection of first-aiders	:	and use the recor when the potentia	ers should pay attention to self-protection, nmended personal protective equipment Il for exposure exists (see section 8).
	Notes to physician		Treat symptomati	cally and supportively.
	ble extinguishing media	:	Water spray Alcohol-resistant Carbon dioxide (C Dry chemical	
Unsu media	itable extinguishing a	:	None known.	
Spec fightir	ific hazards during fire- ng	:	concentrations, and potential dust exp	dust; fine dust dispersed in air in sufficient nd in the presence of an ignition source is a losion hazard. bustion products may be a hazard to health.
Haza ucts	Hazardous combustion prod- ucts		Carbon oxides Nitrogen oxides (I Metal oxides Phosphorus comp Oxides of phosph Carbon dioxide (C	oounds orus
Spec ods	ific 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
	ial protective equipment efighters	:		e, wear self-contained breathing apparatus. tective equipment.
6. ACCIDI	ENTAL RELEASE MEA	SUF	RES	
	onal precautions, protec- equipment and emer-	:		tective equipment. ing advice (see section 7) and personal pro-

gency procedures		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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		e L F e r	es, as these may eased into the at local or national bosal of this mate employed in the c nine which regula Sections 13 and 2	build not be allowed to accumulate on surfac- form an explosive mixture if they are re- mosphere in sufficient concentration. regulations may apply to releases and dis- trial, as well as those materials and items leanup of releases. You will need to deter- ations are applicable. IS of this SDS provide information regarding tional requirements.
7. HANDI	ING AND STORAGE			
Tech	nical measures	C F	ausing an explose Provide adequate	nay accumulate and ignite suspended dust sion. precautions, such as electrical grounding nert atmospheres.
Loca	I/Total ventilation	: ľ		ation is unavailable, use with local exhaust
Advid	ce on safe handling	: [[Do not get on skir Do not breathe du Do not swallow. Avoid contact with Handle in accorda practice, based of sessment Keep container tig Minimize dust ger Keep container cl Keep away from h	ust. n eyes. ance with good industrial hygiene and safety n the results of the workplace exposure as-
Conc	litions for safe storage	: H S H	Keep in properly l Store locked up. Keep tightly close	
Mate	rials to avoid	: [ce with the particular national regulations. the following product types: agents

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

:

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis
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-

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		All eng desigr protec No op Totally are rec Opera	eakage of compounds into the workplace. gineering controls should be implemented by facility and operated in accordance with GMP principles to t products, workers, and the environment. en handling permitted. / enclosed processes and materials transport systems quired. tions require the use of appropriate containment tech- / designed to prevent leakage of compounds into the lace.
Perso	onal protective equip	ment	
Fil	ratory protection ter type protection	sure a omme	quate local exhaust ventilation is not available or expo- ssessment demonstrates exposures outside the rec- inded guidelines, use respiratory protection. ulates type
Ма	aterial	Chem	ical-resistant gloves
IVIC	atendi	. Onem	
	emarks rotection	: Wear If the wists Wear	der double gloving. safety glasses with side shields or goggles. work environment or activity involves dusty conditions, or aerosols, wear the appropriate goggles. a faceshield or other full face protection if there is a ial for direct contact to the face with dusts, mists, or ols.
Skin a	and body protection	Additio being suits) Use a	uniform or laboratory coat. onal body garments should be used based upon the tas performed (e.g., sleevelets, apron, gauntlets, disposabl to avoid exposed skin surfaces. ppropriate degowning techniques to remove potentially ninated clothing.
Hygie	ne measures	: If expo flushin place. When Wash The ef engine approp indust	osure to chemical is likely during typical use, provide ey ng systems and safety showers close to the working

Appearance : powder

- Colour : White to light yellow
- Odour : No data available
- Odour Threshold : No data available

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Versic 7.0	n Revision Date: 28.09.2024		S Number: 179-00020	Date of last issue: 30.09.2023 Date of first issue: 02.02.2015
р	Н	:	No data available)
Ν	lelting point/freezing point	:	No data available)
	nitial boiling point and boiling ange	:	No data available	
F	lash point	:	Not applicable	
E	vaporation rate	:	Not applicable	
F	lammability (solid, gas)	:	May form explosi dling or other me	ve dust-air mixture during processing, han- ans.
F	lammability (liquids)	:	No data available)
	lpper explosion limit / Upper ammability limit	:	No data available	
	ower explosion limit / Lower ammability limit	:	No data available	
V	apour pressure	:	Not applicable	
R	elative vapour density	:	Not applicable	
R	elative density	:	No data available)
D	ensity	:	No data available)
S	olubility(ies) Water solubility	:	No data available)
	artition coefficient: n-	:	Not applicable	
	ctanol/water uto-ignition temperature	:	No data available)
D	ecomposition temperature	:	No data available)
V	iscosity Viscosity, kinematic	:	Not applicable	
E	xplosive properties	:	Not explosive	
C	Dxidizing properties	:	The substance or	r mixture is not classified as oxidizing.
	article characteristics article size	:	No data available	
10. S1	ABILITY AND REACTIVITY	,		
	eactivity hemical stability	:	Not classified as Stable under nor	a reactivity hazard. mal conditions.

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ersion .0	Revision Date: 28.09.2024		S Number:)79-00020	Date of last issue: 30.09.2023 Date of first issue: 02.02.2015			
Poss tions	ibility of hazardous reac-	:	dling or other me	ive dust-air mixture during processing, han eans. trong oxidizing agents.			
Cond	litions to avoid	:	Heat, flames and				
Haza	Incompatible materials Hazardous decomposition products		Avoid dust formation.Oxidizing agentsNo hazardous decomposition products are known.				
1. TOXIO	COLOGICAL INFORMAT		I				
Inforr expo	nation on likely routes of sure	:	Inhalation Skin contact Ingestion Eye contact				
	e toxicity						
Not c	lassified based on availa	ble i	nformation.				
Prod							
Acute	e oral toxicity	:	Acute toxicity est Method: Calculat	imate: > 5,000 mg/kg ion method			
<u>Com</u>	ponents:						
Glyc	ine:						
	e oral toxicity	:	LD50 (Mouse, fei	male): 4,920 mg/kg			
-	corrosion/irritation es mild skin irritation.						
<u>Com</u>	ponents:						
Glyc	ine:						
Spec	ies	:	Rabbit				
Meth		:	OECD Test Guid	eline 404			
Resu Rema		:	No skin irritation Based on data fro	om similar materials			
Inter	feron alfa-2b:						
Spec		:	Rat				
Resu		:	Skin irritation				
	ous eye damage/eye irri lassified based on availa						
<u>Com</u>	ponents:						
Glyc	ine:						
Spec	ies	:	Rabbit				
Meth Resu		:	OECD Test Guid No eye irritation	eline 405			

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/ersion 7.0	Revision Date: 28.09.2024		0S Number: 079-00020	Date of last issue: 30.09.2023 Date of first issue: 02.02.2015				
Rema	Remarks		: Based on data from similar materials					
Interf	feron alfa-2b:							
	Species Remarks		Rabbit slight irritation					
Resp	iratory or skin sensi	tisatio	on					
•••••	sensitisation							
	lassified based on ava		information.					
-	iratory sensitisation lassified based on ava		information.					
Com	ponents:							
Glyci	ine:							
	sure routes	:	Skin contact	de assay (LLNA)				
Speci Metho Resu	od	:	Mouse OECD Test Gui negative	deline 429				
	n cell mutagenicity lassified based on ava	ailable	information.					
Com	ponents:							
Glyci								
Geno	toxicity in vitro	:	Test Type: Bact	terial reverse mutation assay (AMES				
			Method: OECD Result: negative	Test Guideline 471				
			Result: negative Test Type: In vi	Test Guideline 471 e tro mammalian cell gene mutation te Test Guideline 476				
			Result: negative Test Type: In vi Method: OECD Result: negative	Test Guideline 471 e tro mammalian cell gene mutation te Test Guideline 476 e omosome aberration test in vitro				
Interf	feron alfa-2b:		Result: negative Test Type: In vi Method: OECD Result: negative Test Type: Chro	Test Guideline 471 tro mammalian cell gene mutation te Test Guideline 476 omosome aberration test in vitro				
		:	Result: negative Test Type: In vi Method: OECD Result: negative Test Type: Chro Result: negative	Test Guideline 471 e tro mammalian cell gene mutation te Test Guideline 476 e omosome aberration test in vitro e omosome aberration test in vitro				
	ieron alfa-2b:	:	Result: negative Test Type: In vi Method: OECD Result: negative Test Type: Chro Result: negative Test Type: Chro Result: negative	Test Guideline 471 e tro mammalian cell gene mutation te Test Guideline 476 e omosome aberration test in vitro e omosome aberration test in vitro e terial reverse mutation assay (AMES				

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	inogenicity lassified based on avai	lable	information.	
-	oductive toxicity damage fertility. May da	amag	e the unborn child.	
Com	ponents:	-		
Glyci	ine:			
Effec ment	ts on foetal develop-	:	Test Type: Embry Species: Rat Application Route Result: negative	vo-foetal development :: Ingestion
Inter	feron alfa-2b:			
Effec	ts on fertility	:	Test Type: Fertilit Species: Monkey Fertility: LOAEL: 3 Result: menstrual Remarks: Abortio	3.8 μg/kg I irregularities
Effec ment	ts on foetal develop-	:	Species: Monkey	y/early embryonic development oxicity: LOAEL: 3.8 μg/kg body weight thal effects
Repro sessr	oductive toxicity - As- ment	:	May damage ferti	lity. May damage the unborn child.
	F - single exposure lassified based on avail	lable	information.	
STO	Г - repeated exposure			
May	cause damage to organ	ıs (Bl	ood, Bone marrow) through prolonged or repeated exposure.
Com	ponents:			
Targe	feron alfa-2b: et Organs ssment	:	Blood, Bone marr May cause dama exposure.	ow ge to organs through prolonged or repeated
Repe	ated dose toxicity			
Com	ponents:			
Glyci	ino			

Glycine:

Species	: Rat, male
NOAEL	: >= 2,000 mg/kg
Application Route	: Ingestion
Species NOAEL Application Route Exposure time	: 28 Days

Interferon alfa-2b:

- Species
- : Monkey

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NOA Appli Expo Rem	ication Route osure time		0.095 mg/kg Intramuscular 1 Months No significant a	adverse effects were reported		
NOA Appli Expo	Species NOAEL Application Route Exposure time Remarks		Rat 0.38 mg/kg Subcutaneous 3 Months No significant adverse effects were reported			
	EL ication Route osure time		Mouse 0.076 mg/kg Intraperitoneal 9 d No significant a	adverse effects were reported		
LÒA Appli Expo Targ	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			
Not o	ration toxicity classified based on availa erience with human exp					
Inter	ponents: feron alfa-2b: contact	:	Symptoms: Th toms, Fever, cl	e most common side effects are:, flu-like symp- hills, Fatigue		
	OGICAL INFORMATIO	N				
	ponents:					
Glyc Toxic	ine: city to fish	:	LC50 (Oryzias Exposure time:	latipes (Japanese medaka)): > 1,000 mg/l 96 h		
	city to daphnia and other tic invertebrates	:	Exposure time:	a magna (Water flea)): > 220 mg/l : 48 h 9 Test Guideline 202		

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		1,000 mg/l Exposure tin	ne: 72 h	
Pers	istence and degradab	oility		
<u>Com</u>	ponents:			
Glyc	ine:			
Biode	egradability	Biodegradat Exposure tin	dily biodegradable. ion: 76 - 82 % ne: 14 d CD Test Guideline 301C	
Bioa	ccumulative potential			
<u>Com</u>	ponents:			
Glyc	ine:			
	tion coefficient: n- nol/water	: log Pow: -3.2	21	
Mobi	ility in soil			
No da	ata available			
	r adverse effects ata available			
13. DISPO	OSAL CONSIDERATIO	ONS		
Disn	osal methods			
-	e from residues		ose of waste into sewer. n accordance with local regulations.	
Cont	ominated naclearing		increase and he token to an annroued weater	han

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

Not regulated as a dangerous good

IATA-DGR

Not regulated as a dangerous good

IMDG-Code

Not regulated as a dangerous good

Transport in bulk according to IMO instruments

Not applicable for product as supplied.

Special precautions for user

Not applicable

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15. REGULATORY INFORMATION

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

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

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

16. OTHER INFORMATION

Revision Date	:	28.09.2024
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/

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

Date format : dd.mm.yyyy

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, Evalua-

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tion, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS 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.

IN / EN