

Version 5.2	Revision Date: 28.09.2024	SDS Number: 20511-00025	Date of last issue: 26.09.2023 Date of first issue: 09.10.2014				
SECTION	1. IDENTIFICATION						
Produ	uct identifier	: Peginterfe	: Peginterferon Alfa-2b Powder Formulation				
Manu	afacturer or supplier	s details					
Comp	bany	: MSD					
Addre	ess	n⁰ 1500 –	Avenue Comendador Antônio Loureiro Ramos, nº 1500 – Distrito Industrial Montes Claros – MG, Brazil 39404-620				
Telep	phone	: +55 (38) 3	+55 (38) 3229 7000				
Emer	gency telephone	: +55 (38) 3	+55 (38) 3201 5670				
E-ma	il address	: EHSDATA	STEWARD@msd.com				
Reco	ommended use of the	e chemical and rea	strictions on use				
	mmended use ictions on use	: Pharmace : Not applic					
SECTION	2. HAZARDS IDENT	IFICATION					
GHS	Classification in acc	ordance with ABI	NT NBR 14725 Standard				

Reproductive toxicity	:	Category 1B
GHS label elements in acco	ordaı	nce with ABNT NBR 14725 Standard
Hazard pictograms	:	
Signal Word	:	Danger
Hazard Statements	:	H360FD May damage fertility. May damage the unborn child.
Precautionary Statements	:	<b>Prevention:</b> P201 Obtain special instructions before use. P280 Wear protective gloves/ protective clothing/ eye protec- tion/ face protection.
		Response: P308 + P313 IF exposed or concerned: Get medical advice/ attention.
		Storage: P405 Store locked up.



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

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

#### SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

#### Components

•			
Chemical name	CAS-No.	Classification	Concentration (% w/w)
Sucrose	57-50-1		>= 90 -<= 100
Peginterferon Alfa-2b	215647-85-1	Repr., 1B STOT RE, (Gastroin- testinal tract, Immune system, Cardio- vascular system, En- docrine system, Cen- tral nervous system, Liver, Respiratory Tract, Eye), 1	>= 0,3 -< 1

#### **SECTION 4. 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.
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	:	If in eyes, rinse well with water. Get medical attention if irritation develops and persists.
If swallowed	:	If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water.
Most important symptoms and effects, both acute and delayed	:	May damage fertility. May damage the unborn child. Contact with dust can cause mechanical irritation or drying of the skin. Dust contact with the eyes can lead to mechanical irritation.
Protection of first-aiders	:	First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
Notes to physician	:	Treat symptomatically and supportively.

#### **SECTION 5. FIRE-FIGHTING MEASURES**

Suitable extinguishing media : Water spray



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				Alcohol-resistant f Carbon dioxide (C Dry chemical		
	Unsuita media	ble extinguishing	:	None known.		
	Specific hazards during fire fighting		:	Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard. Exposure to combustion products may be a hazard to health.		
	Hazardous combustion prod- ucts		:	Metal oxides Phosphorus comp Oxides of phosph Carbon oxides		
	Specific extinguishing meth- ods		:	Use extinguishing measures that are appropriate to local or cumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe so. Evacuate area.		
	Special for fire-	protective equipment fighters	:	In the event of fire Use personal prot	e, wear self-contained breathing apparatus. ective equipment.	

### SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protec- tive equipment and emer- gency procedures	:	Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective 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 container 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 surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.



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SECTION	I 7. HANDLING AND ST	ORAGE	
Tech	nical measures	causing an expl Provide adequa	may accumulate and ignite suspended dust osion. te precautions, such as electrical grounding inert atmospheres.
Loca	I/Total ventilation		ilation is unavailable, use with local exhaust
Advice on safe handling		: Do not get on sl Do not breathe Do not swallow. Avoid contact w Handle in accor practice, based assessment Keep container Minimize dust g Keep container Keep away from Take precautior	dust. ith eyes. dance with good industrial hygiene and safety on the results of the workplace exposure
Hygi	ene measures	flushing system place. When using do	hemical is likely during typical use, provide eye s and safety showers close to the working not eat, drink or smoke. ated clothing before re-use.
Conc	ditions for safe storage	y labeled containers. sed. ance with the particular national regulations.	
Mate	rials to avoid	: Do not store wit Strong oxidizing	h the following product types: agents bstances and mixtures

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis
Sucrose	57-50-1	TWA	10 mg/m <sup>3</sup>	ACGIH
Peginterferon Alfa-2b	215647-85-1	TWA (inhal- able fraction)	0.2 μg/m3 (OEB 5)	Internal

#### Engineering measures

: Minimize workplace exposure concentrations. Apply measures to prevent dust explosions. Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are



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			work area (i.e., th	nner to prevent the escape of dust into the ere is no leakage from the equipment). ation is unavailable, use with local exhaust		
Pers	onal protective equipr	nent				
Resp	Respiratory protection		If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.			
	lter type I protection	: Particulates type				
M	Material		Chemical-resistant gloves			
R	emarks	:	: Choose gloves to protect hands against chemicals de on the concentration specific to place of work. Breaktl time is not determined for the product. Change gloves For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protect gloves with the glove manufacturer. Wash hands befor breaks and at the end of workday.			
Eye p	protection	:	: Wear the following personal protective equipment: Safety goggles			
Skin	and body protection	:	<ul> <li>Select appropriate protective clothing based on chemi resistance data and an assessment of the local expos potential.</li> <li>Skin contact must be avoided by using impervious pro clothing (gloves, aprons, boots, etc).</li> </ul>			

#### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state	:	powder
Color	:	White to light yellow
Odor	:	No data available
Odor Threshold	:	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	:	No data available
Evaporation rate	:	No data available
Flammability (solid, gas)	:	May form explosive dust-air mixture during processing, handling or other means.
Flammability (liquids)	:	No data available



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		explosion limit / Upper bility limit	:	No data available	
		explosion limit / Lower bility limit	:	No data available	
	Vapor p	pressure	:	No data available	)
	Relative	e vapor density	:	No data available	)
	Density	,	:	1 g/cm <sup>3</sup>	
	Solubili Wat	ty(ies) er solubility	:	No data available	•
	Partitio octanol	n coefficient: n-	:	No data available	)
		nition temperature	:	No data available	)
	Decom	position temperature	:	No data available	)
	Viscosi Visc	ty cosity, dynamic	:	No data available	)
	Visc	osity, kinematic	:	No data available	9
	Explosi	ve properties	:	Not explosive	
	Oxidiziı	ng properties	:	The substance of	mixture is not classified as oxidizing.
	Molecu	lar weight	:	No data available	)
	Particle Particle	e characteristics e size	:	No data available	

### SECTION 10. STABILITY AND REACTIVITY

Reactivity Chemical stability Possibility of hazardous reac- tions	:	Not classified as a reactivity hazard. Stable under normal conditions. May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.
Conditions to avoid	:	Heat, flames and sparks. Avoid dust formation.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.

### SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of	:	Inhalation
exposure		Skin contact



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			Ingestion Eye contact	
Acute	e toxicity			
Not cl	assified based on availa	ble	information.	
Comp	oonents:			
Sucro	ose:			
Acute	oral toxicity	:	LD50 (Rat): 29.70	0 mg/kg
Pegin	terferon Alfa-2b:			
	toxicity (other routes of istration)	:	LD50 (Rat): > 20, Application Route	
			LD50 (Monkey): >	9,8 mg/kg
-	corrosion/irritation		1. <b>f</b>	
	assified based on availa	DIE	information.	
	oonents:			
Pegin Speci	terferon Alfa-2b:		Rabbit	
Resul		:	Mild skin irritation	
	us eye damage/eye irri			
Not cl	us eye damage/eye irri assified based on availa ponents:			
Not cla <u>Comp</u>	assified based on availa			
Not cla Comp Pegin Specie	assified based on availa ponents: nterferon Alfa-2b: es		information. Rabbit	
Not cla <u>Comp</u> Pegin	assified based on availa ponents: nterferon Alfa-2b: es		information.	
Not cla <u>Comp</u> Pegin Specie Result	assified based on availa ponents: nterferon Alfa-2b: es	ble :	information. Rabbit Mild eye irritation	
Not cla <u>Comp</u> Pegin Specie Result Respin Skin s	assified based on availa <u>conents:</u> aterferon Alfa-2b: es t iratory or skin sensitiza sensitization	ble : : atic	information. Rabbit Mild eye irritation <b>n</b>	
Not cla Comp Pegin Specia Result Respin Skin s Not cla	assified based on availa <u>conents:</u> terferon Alfa-2b: es t iratory or skin sensitiza sensitization assified based on availa	ble : : atic	information. Rabbit Mild eye irritation <b>n</b>	
Not cla <u>Comp</u> Pegin Specie Result Respin Skin s Not cla Respin	assified based on availa <u>conents:</u> aterferon Alfa-2b: es t iratory or skin sensitiza sensitization	ble : : ble	information. Rabbit Mild eye irritation <b>n</b> information.	
Not cla Comp Pegin Specie Respi Respi Skin s Not cla Respi Not cla Germ	assified based on availa <u>conents:</u> terferon Alfa-2b: es t iratory or skin sensitization assified based on availa iratory sensitization	ble : atic ble	information. Rabbit Mild eye irritation on information. information.	
Not cla Comp Pegin Specie Respi Respi Skin s Not cla Respi Not cla Germ Not cla	assified based on availa <u>conents:</u> terferon Alfa-2b: es t iratory or skin sensitization assified based on availa iratory sensitization assified based on availa cell mutagenicity	ble : atic ble	information. Rabbit Mild eye irritation on information. information.	
Not cla Comp Pegin Specie Respi Respi Skin s Not cla Respi Not cla Germ Not cla	assified based on availa <u>conents:</u> terferon Alfa-2b: es t iratory or skin sensitization assified based on availa iratory sensitization assified based on availa cell mutagenicity assified based on availa cell mutagenicity assified based on availa cell mutagenicity assified based on availa	ble : atic ble	information. Rabbit Mild eye irritation on information. information.	
Not cla Comp Pegin Specie Result Respi Skin s Not cla Germ Not cla Comp Sucro	assified based on availa <u>conents:</u> terferon Alfa-2b: es t iratory or skin sensitization assified based on availa iratory sensitization assified based on availa cell mutagenicity assified based on availa cell mutagenicity assified based on availa cell mutagenicity assified based on availa	ble : atic ble	information. Rabbit Mild eye irritation on information. information.	o mammalian cell gene mutation tes
Not cla Comp Pegin Specie Result Respi Skin s Not cla Respi Not cla Germ Not cla Comp Sucro Genot	assified based on availa <u>conents:</u> terferon Alfa-2b: es t iratory or skin sensitization assified based on availa iratory sensitization assified based on availa cell mutagenicity assified based on availa cell mutagenicity assified based on availa based on availa	ble : atic ble	information. Rabbit Mild eye irritation on information. information. information. Test Type: In vitro	o mammalian cell gene mutation tes



ersion 2	Revision Date: 28.09.2024	-	S Number: 511-00025	Date of last issue: 26.09.2023 Date of first issue: 09.10.2014
			Result: negative	)
				omosomal aberration uman lymphocytes
Geno	toxicity in vivo	:	Test Type: In vir Species: Mouse Result: negative	
	nogenicity assified based on avai	ilable i	information.	
Repro	oductive toxicity			
-	lamage fertility. May da	amage	e the unborn chil	d.
<u>Com</u>	oonents:			
Pegir	terferon Alfa-2b:			
-	s on fertility	:	Species: Monke Application Rou Dose: 0.35 milli	lity/early embryonic development ey, female te: Subcutaneous gram per kilogram ect on estrous cycle
Repro sessn	oductive toxicity - As- nent	:	animal experime	of adverse effects on development, based on ents., Clear evidence of adverse effects on and fertility, based on animal experiments.
	-single exposure assified based on avai	ilable i	information.	
	-repeated exposure			
	assified based on avai conents:	liable	information.	
-	nterferon Alfa-2b: ht Organs	:	tem, Endocrine	tract, Immune system, Cardio-vascular sys- system, Central nervous system, Liver, Res-
Asses	ssment	:	piratory Tract, E Causes damage exposure.	e to organs through prolonged or repeated
Repe	ated dose toxicity			
<u>Com</u>	oonents:			
Pegir	terferon Alfa-2b:			
Speci NOAE	es EL cation Route	:	Mouse 0,0038 mg/kg Subcutaneous 9 d	
	sure time	:	ษน	



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	EL cation Route sure time	: 0,0042 mg/kg : Subcutaneou : 30 d				
Expo Targe Spec NOAI LOAE Expo	EL cation Route sure time et Organs ies EL	: Monkey : 0,015 mg/kg : 0,077 mg/kg : 3 Months	marrow, Immune system Fract, Cardio-vascular system, Central nervous			
Not c	Aspiration toxicity Not classified based on available information.					
-	Experience with human exposure <u>Components:</u>					
	nterferon Alfa-2b:		u-like symptoms, Gastrointestinal disturbance, ession, tingling			
SECTION	12. ECOLOGICAL IN	FORMATION				
Ecot	oxicity					
	ponents:					
	nterferon Alfa-2b:					
Ecoto	oxicology Assessme	nt				
Acute	aquatic toxicity	: No data avai	lable			
Chror	nic aquatic toxicity	: No data avai	lable			
Persi	stence and degradal	oility				
<u>Com</u>	ponents:					
Pegir	nterferon Alfa-2b:					
Biode	gradability	Biodegradati Exposure tim				



ersion 2	Revision Date: 28.09.2024	SDS Number: 20511-00025	Date of last issue: 26.09.2023 Date of first issue: 09.10.2014
Bioad	cumulative potential		
<u>Com</u>	oonents:		
Sucro	ose:		
	ion coefficient: n- ol/water	: Pow: < 1	
	<b>lity in soil</b> ata available		
	r <b>adverse effects</b> ata available		
CTION	13. DISPOSAL CONSI	DERATIONS	
Dispo	osal methods		
•	e from residues		e of waste into sewer.
Conta	aminated packaging	: Empty contain handling site for	accordance with local regulations. ers should be taken to an approved waste or recycling or disposal. e specified: Dispose of as unused product.
CTION	14. TRANSPORT INFO		
Interr	national Regulations		
UNR Not re	<b>FDG</b> egulated as a dangerou	s good	
IATA Not re	-DGR egulated as a dangerou	s good	
-	<b>-Code</b> egulated as a dangerou	s good	
	sport in bulk according pplicable for product as	-	RPOL 73/78 and the IBC Code
Dome	estic regulation		
<b>ANTT</b> Not re	egulated as a dangerou	s good	
-	ial precautions for use	er	
Not a	pplicable		
CTION	15. REGULATORY IN	FORMATION	
Safet mixtu		mental regulations/	legislation specific for the substance or
	nal List of Carcinogenic	Agents for Humans	- : Not applicable

(LINACH) Brazil. List of chemicals controlled by the Federal : Not applicable Police



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	The in AICS	gredients of this proc	luct :	are reported in the not determined	ne following inventories:
	DSL		:	not determined	
	IECSC		:	not determined	
SEC	CTION 1	6. OTHER INFORMAT		1	
	Revisio Date fo	on Date ormat	:	28.09.2024 dd.mm.yyyy	
	Furthe	r information			
		es of key data used to e the Material Safety heet	:		data, data from raw material SDSs, OECD arch results and European Chemicals Agen- ropa.eu/
	Full te	xt of other abbreviation	ons		
	ACGIH		:	USA. ACGIH Thre	eshold Limit Values (TLV)
	ACGIH	/ TWA	:	8-hour, time-weig	hted average
<ul> <li>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 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 Substance; e; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No</li> </ul>					

es; (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 Recom-



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mendations 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 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.

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