according to GB/T 16483 and GB/T 17519



Peginterferon Alfa-2b Redipen Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2024/04/06
5.0	2024/09/28	19423-00023	Date of first issue: 2014/10/07

1. PRODUCT AND COMPANY IDENTIFICATION

Product name :	Peginterferon Alfa-2b Redipen Formulation			
Manufacturer or supplier's details Company : MSD				
Address :	199 Wenhai North Road HEDA, Hangzhou - Zhejiang Province - CHINA 31001	8		
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	:	powder off-white No data available
May damage fertility. May dam	age	e the unborn child. Harmful to aquatic life.
GHS Classification		
Reproductive toxicity	:	Category 1B
Short-term (acute) aquatic hazard	:	Category 3
GHS label elements		
Hazard pictograms	:	
Signal word	:	Danger
Hazard statements	:	H360FD May damage fertility. May damage the unborn child. H402 Harmful to aquatic life.

according to GB/T 16483 and GB/T 17519



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Precautionary statements

Prevention:

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P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P273 Avoid release to the environment.
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.

Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

Physical and chemical hazards

Not classified based on available information.

Health hazards

May damage fertility. May damage the unborn child.

Environmental hazards

Harmful to aquatic life.

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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
α-D-Glucopyranoside, α-D-glucopyranosyl,	6138-23-4	>= 90 -<= 100
dihydrate		
Peginterferon Alfa-2b	215647-85-1	>= 0.3 -< 1

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.

according to GB/T 16483 and GB/T 17519



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In case of skin contact		:	Get medical attention. 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.		
	In case	of eye contact	:	If in eyes, rinse w	
	If swalle	bewc	:	If swallowed, DO Get medical atten	
		nportant symptoms ects, both acute and d	:	 Rinse mouth thoroughly with water. May damage fertility. May damage the unborn child. Contact with dust can cause mechanical irritation or drying the skin. 	
	Protect	ion of first-aiders	:	First Aid responde and use the recor	the eyes can lead to mechanical irritation. ers should pay attention to self-protection, nmended personal protective equipment
	Notes t	o physician	:		Il for exposure exists (see section 8). cally and supportively.
5. F	5. FIREFIGHTING MEASURES				
	Suitable	e extinguishing media	:	Water spray Alcohol-resistant Carbon dioxide (C Dry chemical	
	Unsuita media	ble extinguishing	:	None known.	
	Specific fighting	c hazards during fire-	:	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. pustion products may be a hazard to health.
	Hazard ucts	ous combustion prod-	:	Carbon oxides	
	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 firefi	protective equipment ighters	:		e, wear self-contained breathing apparatus. tective equipment.

6. ACCIDENTAL RELEASE MEASURES

according to GB/T 16483 and GB/T 17519

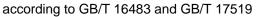


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tive eq gency	nal precautions, protec- uipment and emer- procedures nmental precautions	:	tective equipment Avoid release to th Prevent further lea Retain and dispos	ing advice (see section 7) and personal pro- recommendations (see section 8). The environment. akage or spillage if safe to do so. be of contaminated wash water. should be advised if significant spillages
	Methods and materials for containment and cleaning up		tainer for disposal Avoid dispersal of with compressed a Dust deposits sho es, as these may leased into the atr Local or national r posal of this mate employed in the c mine which regula Sections 13 and 1	dust in the air (i.e., clearing dust surfaces

7. HANDLING AND STORAGE

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.
Avoidance of contact	:	Oxidizing agents





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Stor	•		
Conditions for safe storage		: Keep in properly Store locked up. Keep tightly clos	
Mate	erials to avoid		nce with the particular national regulations. n the following product types: agents

Packaging material	: Unsuitable material: None known.
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8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis
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 de- signed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment). If sufficient ventilation is unavailable, use with local exhaust ventilation.
Personal protective equipment	
Respiratory protection :	If adequate local exhaust ventilation is not available or expo- sure assessment demonstrates exposures outside the rec- ommended guidelines, use respiratory protection.
	Particulates type
Eye/face protection :	Wear the following personal protective equipment: Safety goggles
Skin and body protection :	Select appropriate protective clothing based on chemical resistance data and an assessment of the local exposure potential. Skin contact must be avoided by using impervious protective clothing (gloves, aprons, boots, etc).
Hand protection	
Material :	Chemical-resistant gloves
Remarks :	Choose gloves to protect hands against chemicals depending on the concentration and quantity of the hazardous sub- stance and specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the

according to GB/T 16483 and GB/T 17519



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Hy	Hygiene measures		 glove manufacturer. Wash hands before breaks and a end of workday. If exposure to chemical is likely during typical use, proeye flushing systems and safety showers close to the ing place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use. 			
9. PHY	SICAL AND CHEMICAL PI	ROF	PERTIES			
Ap	opearance	:	powder			
Co	blour	:	off-white			
0	dour	:	No data available	9		
0	dour Threshold	:	No data available	e		
pH	1	:	No data available	9		
M	elting point/freezing point	:	No data available	9		
	tial boiling point and boiling nge	:	No data available	e		
Fl	ash point	:	No data available	e		
E١	aporation rate	:	No data available	9		
Fl	ammability (solid, gas)	:	May form explos dling or other me	ive dust-air mixture during processing, han- eans.		
Fl	ammability (liquids)	:	No data available	e		
	oper explosion limit / Upper mmability limit	:	No data available	9		
	wer explosion limit / Lower mmability limit	:	No data available	e		
Va	apour pressure	:	No data available	9		
Re	elative vapour density	:	No data available	e		
Re	elative density	:	No data available	e		
So	blubility(ies) Water solubility	:	soluble			
	artition coefficient: n- tanol/water	:	No data available	e		
	ito-ignition temperature	:	No data available	e		

according to GB/T 16483 and GB/T 17519



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	mposition temperature	: No data av	ailable		
Visco Vis	sity scosity, kinematic	: No data av	No data available		
Explo	sive properties	: Not explos	ive		
Oxidi	zing properties	: The substa	ance or mixture is not classified as oxidizing.		
Moleo	cular weight	: No data av	ailable		
	ele characteristics ele size	: No data av	ailable		
10. STAB	LITY AND REACTIVITY	,			
	tivity nical stability bility of hazardous reac-	: Stable und : May form e dling or oth	ed as a reactivity hazard. er normal conditions. explosive dust-air mixture during processing, han- ner means. with strong oxidizing agents.		
Cond	itions to avoid	: Heat, flames and sparks. Avoid dust formation.			
	npatible materials rdous decomposition icts	: Oxidizing a	 Avoid dust formation. Oxidizing agents No hazardous decomposition products are known. 		
11. TOXIC		ION			
Expo	sure routes	: Inhalation Skin contact Ingestion Eye contact			
	e toxicity lassified based on availa	ble information.			
Com	oonents:				
	Glucopyranoside, α-D-g e oral toxicity	: LD50 (Rat):	dihydrate: > 16,000 mg/kg CD Test Guideline 401		
Pegir	nterferon Alfa-2b:				
	e toxicity (other routes of histration)		> 20.1 mg/kg Route: Intravenous		
		LD50 (Mon	key): > 9.8 mg/kg		
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according to GB/T 16483 and GB/T 17519



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Skin corrosion/irritation

Not classified based on available information.

Components:

α -D-Glucopyranoside, α -D-glucopyranosyl, dihydrate:

Species : Method : Result :	Rabbit
Method :	OECD Test Guideline 404
Result :	No skin irritation

Peginterferon Alfa-2b:

Species Result	:	Rabbit
Result	:	Mild skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

Components:

α -D-Glucopyranoside, α -D-glucopyranosyl, dihydrate:

Species Result Method	:	Rabbit
Result	:	No eye irritation
Method	:	OECD Test Guideline 405

Peginterferon Alfa-2b:

Species Result	:	Rabbit
Result	:	Mild eye 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:

α -D-Glucopyranoside, α -D-glucopyranosyl, dihydrate:

Genotoxicity in vitro	: Test Type: Bacterial reverse mutation assay (AMES) Method: OECD Test Guideline 471 Result: negative
	Test Type: In vitro mammalian cell gene mutation test Method: OECD Test Guideline 476

according to GB/T 16483 and GB/T 17519



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Genc	otoxicity in vivo	Test Ty Result: : Test Ty cytoger Species Applica	: negative ype: Chromosome aberration test in vitro : negative ype: Mutagenicity (in vivo mammalian bone-marrow netic test, chromosomal analysis) es: Mouse ation Route: Intraperitoneal injection : negative
Peqi	nterferon Alfa-2b:		
	otoxicity in vitro		ype: reverse mutation assay : negative
		Test sy	ype: Chromosomal aberration ystem: Human lymphocytes : negative
Geno	otoxicity in vivo	Specie	ype: In vivo micronucleus test es: Mouse : negative
	inogenicity lassified based on ava	ilable informat	tion.
-	oductive toxicity damage fertility. May d	amage the un	ıborn child.
Com	ponents:		
	Glucopyranoside, α-D ts on fertility	: Test Ty Species Applica Method	ype: Two-generation reproduction toxicity study
Effec ment	ts on foetal develop-	Species Applica Methoc	ype: Embryo-foetal development es: Rat ation Route: Ingestion d: OECD Test Guideline 414 : negative
Pegiı	nterferon Alfa-2b:		
Effec	ts on fertility	Species Applica Dose: (ype: Fertility/early embryonic development es: Monkey, female ation Route: Subcutaneous 0.35 milligram per kilogram oms: Effect on estrous cycle

according to GB/T 16483 and GB/T 17519



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Repro	oductive toxicity - As- nent	animal expe	nce of adverse effects on development, based or riments., Clear evidence of adverse effects on ion and fertility, based on animal experiments.			
	Γ - single exposure lassified based on ava	ailable information.				
STO	Γ - repeated exposur	e				
	lassified based on ava					
Com	ponents:					
Pegir	nterferon Alfa-2b:					
Targe	et Organs		inal tract, Immune system, Cardio-vascular sys- ine system, Central nervous system, Liver, Res- ct, Eye			
Asse	ssment	: Causes dan exposure.	Causes damage to organs through prolonged or repeated			
-	eated dose toxicity ponents:					
α-D-0	Glucopyranoside, α-	D-glucopyranosyl,	dihydrate:			
	EL cation Route sure time	: Mouse : 8,289 mg/kg : Ingestion : 90 Days : OECD Test	g Guideline 408			
Pegir	nterferon Alfa-2b:					
Speci NOAI Applie	ies	: Mouse : 0.0038 mg/ł : Subcutaneo : 9 d				
			0.0042 mg/kg Subcutaneous			
llo						

Species LOAEL Application Route Exposure time Target Organs		Monkey 0.12 mg/kg Subcutaneous 30 d Blood, Bone marrow, Immune system
Species NOAEL	:	Monkey 0.015 mg/kg

according to GB/T 16483 and GB/T 17519



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	L sure time t Organs		0.077 mg/kg 3 Months Respiratory Tract system, Bone ma	, Cardio-vascular system, Central nervous rrow	
-	ation toxicity assified based on availa	able	information.		
Expe	rience with human exp	osi	ure		
Comp	oonents:				
Peginterferon Alfa-2b:			Symptoms: flu-like symptoms, Gastrointestinal disturbance, mental depression, tingling		
12. ECOLOGICAL INFORMATION					
Ecoto	oxicity				
Comp	oonents:				
α-D-G	ilucopyranoside, α-D-g	gluc	opyranosyl, dihyo	drate:	
Toxici	ty to fish	:	LC50 (Danio reric Exposure time: 96	o (zebra fish)): > 100 mg/l S h	
	ty to daphnia and other ic invertebrates	:	EC50 (Daphnia m Exposure time: 48 Method: OECD T		
Toxici plants	ty to algae/aquatic	:	ErC50 (Desmode Exposure time: 72 Method: OECD T		
			EC10 (Desmodes	mus subspicatus (green algae)): 13.82 mg/l	

Peginterferon Alfa-2b:

Ecotoxicology Assessment

Acute aquatic toxicity	:	No data available
Acute aquatic toxicity Chronic aquatic toxicity	:	No data available

Persistence and degradability

Components:

н

 α -D-Glucopyranoside, α -D-glucopyranosyl, dihydrate:

Exposure time: 72 h

Method: OECD Test Guideline 201

according to GB/T 16483 and GB/T 17519



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Biode	egradability	: Result:	Not readily biodegradable.		
			radation: 68 - 74 % ure time: 28 d		
Peqi	nterferon Alfa-2b				
	Peginterferon Alfa-2b: Biodegradability :		Result: Readily biodegradable. Biodegradation: 63 % Exposure time: 28 d Method: OECD Test Guideline 301B		
Bioa	ccumulative potential				
Com	ponents:				
α-D-0	Glucopyranoside, α-D-	glucopyrano	osyl, dihydrate:		
Partit	ion coefficient: n- nol/water	: log Pow			
	lity in soil ata available				
	r adverse effects ata available				
13. DISPO	SAL CONSIDERATIO	NS			
Disp	osal methods				
Wast	e from residues		dispose of waste into sewer. e of in accordance with local regulations.		
Conta	aminated packaging	: Empty of dling sit	containers should be taken to an approved waste han- te for recycling or disposal. therwise specified: Dispose of as unused product.		
14. TRAN	SPORT INFORMATION	1			
Inter	national Regulations				
	-				
UNR [.] UN n	umber	· Not ann	olicable		
	er shipping name	: Not applicable : Not applicable			
Class		: Not applicable			
	idiary risk	: Not applicable			
	ing group	p : Not applicable : Not applicable			
	Labels : Not applicable Environmentally hazardous : no				

Environmentally hazardous	:	no
IATA-DGR UN/ID No. Proper shipping name		Not applicable Not applicable

according to GB/T 16483 and GB/T 17519



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Class Subsidi Packing Labels	ary risk g group	 Not applicable Not applicable Not applicable Not applicable Not applicable 	

Labels Packing instruction (cargo aircraft) Packing instruction (passen- ger aircraft)	:	Not applicable Not applicable Not applicable
IMDG-Code UN number Proper shipping name Class Subsidiary risk Packing group Labels EmS Code	:	Not applicable Not applicable Not applicable Not applicable Not applicable Not applicable Not applicable
Marine pollutant	:	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				
Catalogue of Hazardous Chemicals : 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.				
Identification of Major Hazard Installations for Hazardous Chemicals (GB : Not listed				
Hazardous Chemicals for Priority Management under : Not listed				

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SAWS

Regulations on Labour Prot	ection in Workplaces w	her	e Toxic Substances are Used
Catalogue of Highly Toxic Che	emicals	:	Not listed
Regulation of Environmenta and Export of Toxic Chemic	-	irst	Import of Chemicals and the Import
China Severely Restricted Tox and Export	kic Chemicals for Import	:	Not listed
Regulation on the Administr	ration of Precursor Che	mic	als
Catalogue and Classification of	of Precursor Chemicals	:	Not listed
Yangtze River Protection La	w		
This product does not contain	any dangerous chemical	s pr	ohibited for inland river transport.
The components of this pro-	duct are reported in the	fol	lowing inventories:
AICS	: not determined		
DSL	: not determined		
IECSC	: not determined		

16. OTHER INFORMATION

Revision Date	:	2024/09/28
Further information Sources of key data used to compile the Safety Data	:	Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-
Sheet		cy, 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

: yyyy/mm/dd

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



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- 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.

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