



Version	Revision Date:	SDS Number:	Date of last issue: 20.03.2023
4.1	26.09.2023	19436-00021	Date of first issue: 07.10.2014

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Peginterferon Alfa-2b Redipen Formulation Manufacturer or supplier's details

manufacturer of supplier's details						
Company name of supplier	:	MSD				
Address	:	126 E. Lincoln Avenue				
		Rahway, New Jersey U.S.A. 07065				
Telephone	:	908-740-4000				
Emergency telephone	:	1-908-423-6000				
E-mail address	:	EHSDATASTEWARD@msd.com				
Recommended use of the chemical and restrictions on use						

Recommended use	:	Pharmaceutical
Restrictions on use	:	Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification Reproductive toxicity	Category 1B
GHS label elements Hazard pictograms	
Signal Word	Danger
Hazard Statements	H360FD May damage fertility. May damage the unborn child.
Precautionary Statements	 Prevention: P201 Obtain special instructions before use. P202 Do not handle until all safety precautions have been read and understood. 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.





Version	Revision Date:	SDS Number:	Date of last issue: 20.03.2023
4.1	26.09.2023	19436-00021	Date of first issue: 07.10.2014

Other hazards

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.	Concentration (% w/w)
Peginterferon Alfa-2b	215647-85-1	>= 0.1 -< 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 swallowed	:	If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water.
Most important symptoms and effects, both acute and delayed	:	
Protection of first-aiders	:	
Notes to physician	:	Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical
Unsuitable extinguishing media	•	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.



Peginterferon Alfa-2b Redipen Formulation

Version 4.1	Revision Date: 26.09.2023		OS Number: 436-00021	Date of last issue: 20.03.2023 Date of first issue: 07.10.2014		
Haza ucts	ardous combustion prod-	:	Carbon oxides			
Spec ods	ific extinguishing meth-	:	 Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to so. 			
	ial protective equipment e-fighters	:	Evacuate area. In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.			
SECTION	6. ACCIDENTAL RELE	AS	E MEASURES			
tive e	onal precautions, protece equipment and emer- y procedures	· :	Follow safe hand	tective equipment. ling advice (see section 7) and personal nent recommendations (see section 8).		
Envii	ronmental precautions	:	Retain and dispose	akage or spillage if safe to do so. se of contaminated wash water. should be advised if significant spillages		
	ods and materials for ainment and cleaning up	:	container for disp Avoid dispersal o with compressed Dust deposits sho surfaces, as these released into the Local or national disposal of this m employed in the o determine which Sections 13 and	f dust in the air (i.e., clearing dust surfaces		

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 assessment



Peginterferon Alfa-2b Redipen Formulation

Version 4.1	Revision Date: 26.09.2023	SDS Number: 19436-00021	Date of last issue: 20.03.2023 Date of first issue: 07.10.2014		
		Keep container c Keep away from Take precautiona	ightly closed. eneration and accumulation. closed when not in use. heat and sources of ignition. ary measures against static discharges. vent spills, waste and minimize release to the		
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 contaminated clothing before re-use. 			
Conditions for safe storage		: Keep in properly Store locked up. Keep tightly close	: Keep in properly labeled containers.		
Materia	als to avoid	: Do not store with Strong oxidizing	the following product types: agents stances 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
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 designed 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 equipmen	t
Respiratory protection :	If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
Filter type : Hand protection	Particulates type
Material :	Chemical-resistant gloves
Remarks :	Choose gloves to protect hands against chemicals depending on the concentration specific to place of work. Breakthrough time is not determined for the product. Change gloves often!



Versio 4.1	on	Revision Date: 26.09.2023		S Number: 136-00021	Date of last issue: 20.03.2023 Date of first issue: 07.10.2014
	Eye pro Skin an	tection d body protection	:	resistance to cher gloves with the glo breaks and at the Wear the following Safety goggles Select appropriate resistance data ar potential. Skin contact must	ations, we recommend clarifying the nicals of the aforementioned protective ove manufacturer. Wash hands before end of workday. g personal protective equipment: e protective clothing based on chemical nd an assessment of the local exposure be avoided by using impervious protective aprons, boots, etc).
SECT	FION 9.	PHYSICAL AND CH	EMIC		3
A	Appeara	ance	:	powder	
C	Color		:	off-white	
C	Odor		:	No data available)
C	Odor Th	nreshold	:	No data available)
p	эΗ		:	No data available)
Ν	Melting	point/freezing point	:	No data available	
	nitial bo ange	piling point and boiling	:	No data available	
F	-lash p	oint	:	No data available)
E	Evapora	ation rate	:	No data available)
F	-lamma	ability (solid, gas)	:	May form explosi handling or other	ve dust-air mixture during processing, means.
F	Flamma	ability (liquids)	:	No data available	
		explosion limit / Upper bility limit	:	No data available	
		explosion limit / Lower bility limit	:	No data available	
V	√apor p	ressure	:	No data available)
F	Relative	e vapor density	:	No data available)
F	Relative	e density	:	No data available)
S	Solubilit Wate	ty(ies) er solubility	:	soluble	
	Partitior	n coefficient: n- /water	:	No data available	



Peginterferon Alfa-2b Redipen Formulation

Version 4.1	Revision Date: 26.09.2023		S Number: 436-00021	Date of last issue: 20.03.2023 Date of first issue: 07.10.2014
Autoig	gnition temperature	:	No data available	9
Decor	Decomposition temperature		No data available	9
	sity scosity, kinematic sive properties	:	No data available Not explosive	9
Oxidiz	zing properties	:	The substance o	r mixture is not classified as oxidizing.
Molec	ular weight	:	No data available	9
Partic	le size	:	No data available	9

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 exposure

Inhalation Skin contact Ingestion Eye contact

Acute toxicity

Not classified based on available information.

Components:

Peginterferon Alfa-2b:

LD50 (Monkey): > 9.8 mg/kg

Skin corrosion/irritation

Not classified based on available information.



sion	Revision Date: 26.09.2023	SDS Number: 19436-00021	Date of last issue: 20.03.2023 Date of first issue: 07.10.2014
<u>Comp</u>	oonents:		
Pegin	terferon Alfa-2b:		
Speci		: Rabbit	
Resul	t	: Mild skin irrit	ation
Serio	us eye damage/eye	irritation	
Not cl	assified based on ava	ailable information.	
<u>Comp</u>	oonents:		
Pegin	terferon Alfa-2b:		
Speci		: Rabbit	
Resul	t	: Mild eye irrita	ltion
Resp	iratory or skin sens	itization	
Skin s	sensitization		
Not cl	assified based on ava	ailable information.	
Resp	iratory sensitization		
Not classified based on available information.			
	cell mutagenicity assified based on ava	ailable information.	
Comp	oonents:		
Pegin	terferon Alfa-2b:		
Geno	toxicity in vitro		everse mutation assay
		Result: nega	live
			hromosomal aberration
			Human lymphocytes
		Result: nega	live
Geno	toxicity in vivo		vivo micronucleus test
		Species: Mo Result: nega	
		. toodii nogu	··· -
	nogenicity		
	assified based on av	ailable information.	
•	oductive toxicity		
	lamage fertility. May	damage the unborn of	hild.
<u>Comp</u>	<u>oonents:</u>		
-	terferon Alfa-2b:	_	
Effect	s on fertility	: Test Type: F Species: Mor	ertility/early embryonic development
			oute: Subcutaneous
			nilligram per kilogram
			ffect on estrous cycle



Peginterferon Alfa-2b Redipen Formulation

ersion .1	Revision Date: 26.09.2023	-	S Number: 436-00021	Date of last issue: 20.03.2023 Date of first issue: 07.10.2014
Repro sessr	oductive toxicity - As- nent	:	animal experi	e of adverse effects on development, based on ments., Clear evidence of adverse effects on on and fertility, based on animal experiments.
	F-single exposure lassified based on avai	lable	information.	
	F-repeated exposure lassified based on avai	lable	information.	
Com	ponents:			
-	n terferon Alfa-2b: et Organs	:	tem, Endocrin	al tract, Immune system, Cardio-vascular sys- le system, Central nervous system, Liver, Res-
Asse	ssment	:	 piratory Tract, Eye Causes damage to organs through prolonged or repeate exposure. 	
Repe	ated dose toxicity			
Com	ponents:			
Pegir	nterferon Alfa-2b:			
Speci		:	Mouse	
NOAI Appli	=∟ cation Route	:	0.0038 mg/kg Subcutaneous	
	sure time	:	9 d	5
Spec		:	Rat	
NOA		:	0.0042 mg/kg	
	cation Route sure time	:	Subcutaneous 30 d	S
Spec	ies	:	Monkey	
LÕAE		:	0.12 mg/kg	
	cation Route sure time	:	Subcutaneous 30 d	S
	et Organs	:		narrow, Immune system
Spec	ies	:	Monkey	
NOA		:	0.015 mg/kg	
	₋∟ sure time	:	0.077 mg/kg 3 Months	
	et Organs	:		ract, Cardio-vascular system, Central nervous marrow
Aspii	ration toxicity		system, Bone	marrow

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

Peginterferon Alfa-2b:



Peginterferon Alfa-2b Redipen Formulation

Version 4.1	Revision Date: 26.09.2023		0S Number: 436-00021	Date of last issue: 20.03.2023 Date of first issue: 07.10.2014
Inhala	ation	:	Symptoms: flu-lik mental depressio	e symptoms, Gastrointestinal disturbance, n, tingling
SECTION	12. ECOLOGICAL INF	ORN	IATION	
Ecoto	oxicity			
Comp	oonents:			
Pegir	nterferon Alfa-2b:			
	exicology Assessmen	t :	No data available	
Chror	nic aquatic toxicity	:	No data available	
Persi	stence and degradabi	ility		
Comp	oonents:			
-	nterferon Alfa-2b: Ingradability	:	Result: Readily b Biodegradation: Exposure time: 2 Method: OECD T	63 %
	ccumulative potential ata available			
	l ity in soil ata available			
	r adverse effects ata available			
SECTION	13. DISPOSAL CONS	IDER	ATIONS	
Dispo	osal methods			
-	e from residues	:		f waste into sewer.
Conta	aminated packaging	:	Empty containers handling site for r	ordance with local regulations. should be taken to an approved waste ecycling or disposal. pecified: Dispose of as unused product.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG

Not regulated as a dangerous good

IATA-DGR

Not regulated as a dangerous good





Version 4.1	Revision Date: 26.09.2023	SDS Number: 19436-00021	Date of last issue: 20.03.2023 Date of first issue: 07.10.2014			
	-Code egulated as a danger	ous good				
	Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not applicable for product as supplied.					
Dom	Domestic regulation					
	NOM-002-SCT Not regulated as a dangerous good					
Spec	Special precautions for user					
	pplicable					

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

Federal Law for the control of chemical precursors, : Not applicable essential chemical products and machinery for producing capsules, tablets and pills.

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

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

SECTION 16. OTHER INFORMATION

Revision Date	:	26.09.2023
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;



Peginterferon Alfa-2b Redipen Formulation

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Version	Revision Date:	SDS Number:	Date of last issue: 20.03.2023
4.1	26.09.2023	19436-00021	Date of first issue: 07.10.2014

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

Sources of key data used to compile the Material Safety Data Sheet

Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, http://echa.europa.eu/

The information is considered as correct, but not exhaustive, and will be used only as a guide, which is based in the current knowledge of the substance or mixture, and is applicable to proper safety precautions for the product.

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