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SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier Trade name	: Peginterferon Alfa-2b Redipen Formulation	
1.2 Relevant identified uses of t	he substance or mixture and uses advised agair	າst
Use of the Sub- stance/Mixture	: Pharmaceutical	
Recommended restrictions on use	: Not applicable	
1.3 Details of the supplier of the	safety data sheet	
Company	: MSD Kilsheelan Clonmel Tipperary, IE	
Telephone	: 353-51-601000	
E-mail address of person responsible for the SDS	: EHSDATASTEWARD@msd.com	

1.4 Emergency telephone number

+1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Reproductive toxicity, Category 1B

H360FD: May damage fertility. May damage the unborn child.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms

	·	
Signal word	:	Danger
Hazard statements	:	H360FD child.

May damage fertility. May damage the unborn



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Preca	utionary statements	•	pecial instructions before use. otective gloves/ protective clothing/ eye protec- ion.		
		Response: P308 + P313 II attention.	F exposed or concerned: Get medical advice/		
		Storage: P405 Store loc	ked up.		
Hazardous components which must be listed on the label: Peginterferon Alfa-2b					

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

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

3.2 Mixtures

Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Peginterferon Alfa-2b	215647-85-1	Repr. 1B; H360FD STOT RE 1; H372 (Gastrointestinal tract, Immune sys- tem, Cardio- vascular system, Endocrine system, Central nervous system, Liver, Res- piratory Tract, Eye)	>= 0,3 - < 1



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For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measur	es
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.
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).
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.
4.2 Most important symptoms and	offects, both acute and delayed
Risks :	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.
4.2 Indication of any immediate m	edical attention and special treatment needed
Treatment	Treat symptomatically and supportively.
i realment .	Treat symptomatically and supportively.
SECTION 5: Firefighting measu	ires
5.1 Extinguishing media	
Suitable extinguishing media :	Water spray Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical



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	Unsuita media	able extinguishing	:	None known.	
5.2 S	pecial	hazards arising from	the	substance or mi	xture
Specific hazards during fire- fighting		:	concentrations, a 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	
5.3 A	dvice	for firefighters			
S		protective equipment	:		e, wear self-contained breathing apparatus. tective equipment.
	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

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions	:	Use personal protective equipment. Follow safe handling advice (see section 7) and personal pro- tective equipment recommendations (see section 8).
6.2 Environmental precautions		

Environmental precautions	recautions :	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.

6.3 Methods and material for containment and cleaning up

Methods for 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).
	Dust deposits should not be allowed to accumulate on surfac- es, as these may form an explosive mixture if they are re- leased into the atmosphere in sufficient concentration. Local or national regulations may apply to releases and dis- posal of this material, as well as those materials and items
	employed in the cleanup of releases. You will need to deter-



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		Sections 13 a	egulations are applicable. and 15 of this SDS provide information regarding or national requirements.
	ference to other sections ctions: 7, 8, 11, 12 and 13.		
SECT	ON 7: Handling and st	orage	
7.1 Pre	ecautions for safe handlir	na	
	echnical measures	: Static electric causing an ex Provide adeq	ity may accumulate and ignite suspended dust plosion. uate precautions, such as electrical grounding or inert atmospheres.
Lo	cal/Total ventilation		entilation is unavailable, use with local exhaust
	vgiene measures	 Do not get on Do not breath Do not swallo Avoid contact Handle in acc practice, base sessment Keep contain Minimize dus Keep contain Keep away fr Take precaut Take care to environment. If exposure to flushing system 	w.
			g before re-use.
	nditions for safe storage		-
	eas and containers		erly labelled containers. Store locked up. Keep . Store in accordance with the particular national
Ad	dvice on common storage	Strong oxidiz	substances and mixtures
7.3 Sp	ecific end use(s)		
Sp	pecific use(s)	: No data avail	able



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SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Dust

5 mg/m3 Value type (Form of exposure): TWA (respirable dust) Basis: FOR-2011-12-06-1358

10 mg/m3 Value type (Form of exposure): TWA (total dust) Basis: FOR-2011-12-06-1358

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Peginterferon Alfa- 2b	215647-85- 1	TWA (inhalable fraction)	0.2 μg/m3 (OEB 5)	Internal

8.2 Exposure controls

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 equipment

Eye/face protection Hand protection	:	Wear the following personal protective equipment: Safety goggles Equipment should conform to NS EN 166
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 glove manufacturer. Wash hands before breaks and at the end of workday.
Skin and body protection	:	Select appropriate protective clothing based on chemical re- sistance data and an assessment of the local exposure poten- tial.
Respiratory protection	:	Skin contact must be avoided by using impervious protective clothing (gloves, aprons, boots, etc). If adequate local exhaust ventilation is not available or expo- sure assessment demonstrates exposures outside the rec- ommended guidelines, use respiratory protection.



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Fi	lter type	Equipment sho : Particulates ty	puld conform to NS EN 143 pe (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties			
Physical state	:	powder	
Colour	:	off-white	
Odour	:	No data available	
Odour Threshold	:	No data available	
Melting point/freezing point	:	No data available	
Initial boiling point and boiling range	:	No data available	
Flammability (solid, gas)	:	May form explosive dust-air mixture during processing, han- dling or other means.	
Flammability (liquids)	:	No data available	
Upper explosion limit / Upper flammability limit	:	No data available	
Lower explosion limit / Lower flammability limit	:	No data available	
Flash point	:	No data available	
Auto-ignition temperature	:	No data available	
Decomposition temperature	:	No data available	
рН	:	No data available	
Viscosity Viscosity, kinematic	:	No data available	
Solubility(ies) Water solubility	:	soluble	
Partition coefficient: n- octanol/water	:	No data available	
Vapour pressure	:	No data available	



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Relative density		:	No data available	e
Relativ	ve vapour density	:	No data available	e
Particle characteristics Particle size		:	No data available	e
9.2 Other information				
Explos	sives	:	Not explosive	
Oxidiz	ing properties	:	The substance of	r mixture is not classified as oxidizing.
Evapo	ration rate	:	No data available	e
Molec	ular weight	:	No data available	9
Relativ Particl Par 9.2 Other i Explos Oxidiz Evapo	ve vapour density e characteristics rticle size nformation sives ing properties ration rate	:	No data available No data available Not explosive The substance of No data available	e r mixture is not classified as oxidizing.

SECTION 10: Stability and reactivity

10.1 Reactivity

Not classified as a reactivity hazard.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions	: May form explosive dust-air mixture during processing, han-
	dling or other means. Can react with strong oxidizing agents.
10.4 Conditions to avoid	

10.4 Conditions to avoid

Conditions to avoid

: Heat, flames and sparks. Avoid dust formation.

10.5 Incompatible materials

Materials to avoid : Oxidizing agents

10.6 Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Eye contact

Information on likely routes of	:	Inhalation
exposure		Skin contact
		Inaestion

Acute toxicity

Not classified based on available information.



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Comp	oonents:			
-	terferon Alfa-2b:			
	toxicity (other routes of histration)	:	LD50 (Rat): > 20, Application Route	
			LD50 (Monkey): >	9,8 mg/kg
-	corrosion/irritation assified based on availa	blo	information	
	onents:	Die	iniomation.	
	nterferon Alfa-2b:			
Speci Resul	es	:	Rabbit Mild skin irritation	
	us eye damage/eye irri assified based on availa			
<u>Comp</u>	oonents:			
Pegin	nterferon Alfa-2b:			
Speci Resul		:	Rabbit Mild eye irritation	
Resp	iratory or skin sensitis	atio	n	
-	sensitisation assified based on availa	ble	information.	
-	iratory sensitisation assified based on availa	ble	information.	
	cell mutagenicity assified based on availa	ble	information.	
Comp	oonents:			
Pegir	terferon Alfa-2b:			
Geno	toxicity in vitro	:	Test Type: reverse Result: negative	e mutation assay
			Test Type: Chrom Test system: Hum Result: negative	osomal aberration an lymphocytes
Geno	toxicity in vivo	:	Test Type: In vivo Species: Mouse Result: negative	micronucleus test



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Carcinogenicity

Not classified based on available information.

Reproductive toxicity

May damage fertility. May damage the unborn child.

Components:

Peginterferon Alfa-2b:

Effects on fertility	:	Test Type: Fertility/early embryonic development Species: Monkey, female Application Route: Subcutaneous Dose: 0.35 milligram per kilogram Symptoms: Effect on estrous cycle
Reproductive toxicity - As- sessment	:	Clear evidence of adverse effects on development, based on animal experiments., Clear evidence of adverse effects on sexual function and fertility, based on animal experiments.

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Not classified based on available information.

Components:

Peginterferon Alfa-2b:

Target Organs	:	Gastrointestinal tract, Immune system, Cardio-vascular sys-
		tem, Endocrine system, Central nervous system, Liver, Res-
		piratory Tract, Eye
Assessment	:	Causes damage to organs through prolonged or repeated
		exposure.

Repeated dose toxicity

Components:

Peginterferon Alfa-2b:

Species NOAEL Application Route Exposure time	:	Mouse 0,0038 mg/kg Subcutaneous 9 d
Species NOAEL Application Route Exposure time	:	Rat 0,0042 mg/kg Subcutaneous 30 d
Species LOAEL Application Route Exposure time	:	Monkey 0,12 mg/kg Subcutaneous 30 d



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Targe	get Organs : Blood, Bone marrow, Immune system		marrow, Immune system	
	EL		0,015 mg/kg 0,077 mg/kg 3 Months	
-	ration toxicity			
	lassified based on availa			
	mation on other hazard			
	ocrine disrupting prope	rties		
<u>Prod</u> Asse	l <u>uct:</u> ssment	ered to have REACH Artic (EU) 2017/21	: The substance/mixture does not contain components consid- ered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.	
Expe	erience with human exp	osure		
<u>Com</u>	ponents:			
Pegi i Inhal	nterferon Alfa-2b: ation		u-like symptoms, Gastrointestinal disturbance, ssion, tingling	
SECTIO	N 12: Ecological infor	mation		
12.1 Toxi	city			
<u>Com</u>	ponents:			
Pegi	nterferon Alfa-2b:			
	oxicology Assessment aquatic toxicity	: No data avail	lable	
Chro	nic aquatic toxicity	: No data avail	lable	
12.2 Pers	istence and degradabil	ity		
Com	ponents:			
Pegi	nterferon Alfa-2b:			
D'. 1	1 1 114			

Biodegradability	: Result: Readily biodegradable.
0	Biodegradation: 63 %
	Exposure time: 28 d



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Method: OECD Test Guideline 301B

12.3 Bioaccumulative potential

No data available

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

Product:

Assessment

: This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Endocrine disrupting properties

Product:

Assessment

: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 Other adverse effects

No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product	:	Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities. Do not dispose of waste into sewer.
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.

SECTION 14: Transport information

14.1 UN number or ID number

ADN	:	Not regulated as a dangerous good
ADR	:	Not regulated as a dangerous good
RID	:	Not regulated as a dangerous good



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IMDG		:	Not regulated as	a dangerous good
IATA		:	-	a dangerous good
14.2 UN pr	oper shipping name		J	5 5
ADN			Not regulated as	a dangerous good
ADR			0	a dangerous good
RID			-	a dangerous good
IMDG		:	-	a dangerous good
ΙΑΤΑ		:	-	a dangerous good
14.3 Trans	port hazard class(es)	Ū	5 5
ADN	-		Not regulated as	a dangerous good
ADR		:	-	a dangerous good
RID		:	0	a dangerous good
IMDG		:	e e	a dangerous good
ΙΑΤΑ		:	0	a dangerous good
14.4 Packi	ng group		Ū.	
ADN			Not regulated as	a dangerous good
ADR		:	-	a dangerous good
RID		:	-	a dangerous good
IMDG		:	-	a dangerous good
ΙΑΤΑ	(Cargo)	:	-	a dangerous good
ΙΑΤΑ	(Passenger)	:	Not regulated as	a dangerous good
14.5 Envir	onmental hazards			
Not re	gulated as a dangerou	s go	od	
•	al precautions for us	er		
	me transport in bulk	acco	-	
Rema	rks	:	Not applicable for	product as supplied.
SECTION	15: Regulatory info	orma	ation	

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances,	:	Not applicable
mixtures and articles (Annex XVII) REACH - Candidate List of Substances of Very High	:	Not applicable
Concern for Authorisation (Article 59). REACH - List of substances subject to authorisation	:	Not applicable



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(ex XIV)					
. 0	lation (EC) on substa	nces that deplete the o	ozone	:	Not applicable	
layer	Lation (ELI) 0040/4004				Net explicable	
•	(recast)	l on persistent organic	c pollu-	•	Not applicable	
ment		12 of the European P erning the export and		:	Not applicable	

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.

Not applicable

Other regulations:

Note the Working Environment Act § 4-1 and § 4-2 on requirements for the employer to protect pregnant employees against discomfort and injury as a result of the work situation and the working environment.

Note the regulation on organization, leadership and participation, chapter 12 on the work of children and young people.

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

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

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

Other information	:	Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.
Full text of H-Statements H360FD H372	:	May damage fertility. May damage the unborn child. Causes damage to organs through prolonged or repeated exposure.
Full text of other abbreviation Repr. STOT RE FOR-2011-12-06-1358 FOR-2011-12-06-1358 / TWA	ons : :	Reproductive toxicity Specific target organ toxicity - repeated exposure Norway. Occupational Exposure limits Long term exposure limit

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard



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of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA -European Chemicals Agency; EC-Number - European Community number; 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; 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; 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

Further information

Sources of key data used to :	Internal technical data, data from raw material SDSs, OECD
compile the Safety Data	eChem Portal search results and European Chemicals Agen-
Sheet	cy, http://echa.europa.eu/

H360FD

Classification of the mixture:

Classification procedure: Calculation method

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.

NO / EN

Repr. 1B