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

<b>1.1 Product identifier</b> Trade name	:	Peginterferon Alfa-2b Powder Formulation
1.2 Relevant identified uses of t	he s	substance or mixture and uses advised against
Use of the Sub- stance/Mixture	:	Pharmaceutical
Recommended restrictions on use	:	Not applicable
1.3 Details of the supplier of the	e saf	ety data sheet
Company	:	MSD 120 Moorgate EC2M 6UR London, United Kingdom
Telephone	:	+44 (0) 2081548000
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) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)

Reproductive toxicity, Category 1B

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

#### 2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)

Hazard pictograms

Cianal word



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Hazar	d statements	:	H360FD	May o child.	damage fertility. May damage the unborn
Preca	utionary statements	:	Prevention P201 P280	Obtai Wear	n special instructions before use. protective gloves/ protective clothing/ eye ction/ face protection.
			Response:	:	
			P308 + P31	13 IF attent	exposed or concerned: Get medical advice/ ion.
			<b>Storage:</b> P405	Store	locked 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.

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
Substances with a workplace exposure	e limit :		
Sucrose	57-50-1 200-334-9		>= 90 - <= 100

For explanation of abbreviations see section 16.



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#### **SECTION 4: First aid measures**

4.1 Description of first aid measures					
General advice	<ul> <li>In the case of accident or if you feel unwell, seek medical advice immediately.</li> <li>When symptoms persist or in all cases of doubt seek medical advice.</li> </ul>				
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	<ul> <li>In case of contact, immediately flush skin with soap and plenty of water.</li> <li>Remove contaminated clothing and shoes.</li> <li>Get medical attention.</li> <li>Wash clothing before reuse.</li> <li>Thoroughly clean shoes before reuse.</li> </ul>				
In case of eye contact	: If in eyes, rinse well with water. Get medical attention if irritation develops and persists.				
If swallowed	<ul> <li>If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water.</li> </ul>				
4.2 Most important symptoms and	d effects, 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.				
4.3 Indication of any immediate m	edical attention and special treatment needed				
Treatment	: Treat symptomatically and supportively.				

#### **SECTION 5: Firefighting measures**

#### 5.1 Extinguishing media

Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical
Unsuitable extinguishing media	:	None known.



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#### 5.2 Special hazards arising from the substance or mixture

	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 compounds Oxides of phosphorus Carbon oxides
5.3	Advice for firefighters		
	Special protective equipment for firefighters	:	In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.
	Specific extinguishing meth- ods	:	Use extinguishing measures that are appropriate to local cir- cumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.

#### **SECTION 6:** Accidental release measures

#### 6.1 Personal precautions, protective equipment and emergency procedures

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

#### 6.2 Environmental precautions

Environmental precautions	:	Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water. If spillage enters rivers or watercourses, inform the Environ-
		ment Agency (emergency telephone number 0800 807060).

#### 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- mine which regulations are applicable
		mine which regulations are applicable.

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



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Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

#### 6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

#### **SECTION 7: Handling and storage**

#### 7.1 Precautions for safe 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.
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 contami- nated clothing before re-use.
7.2 Conditions for safe storage, i	ncl	uding any incompatibilities
Requirements for storage areas and containers	:	Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations.
Advice on common storage	:	Do not store with the following product types:

Strong oxidizing agents Self-reactive substances and mixtures Organic peroxides Explosives Gases

#### 7.3 Specific end use(s)

Specific use(s)

: No data available



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#### **SECTION 8: Exposure controls/personal protection**

#### 8.1 Control parameters

#### **Occupational Exposure Limits**

dust of any kind

10 mg/m3 Value type (Form of exposure): TWA (Inhalable) Basis: GB EH40

4 mg/m3 Value type (Form of exposure): TWA (Respirable fraction) Basis: GB EH40

Components	CAS-No.	Value type (Form	Control parameters	Basis
		of exposure)		
Sucrose	57-50-1	TWA	10 mg/m3	GB EH40
		STEL	20 mg/m3	GB EH40
Peginterferon Alfa-	215647-85-	TWA (inhalable	0.2 μg/m3 (OEB 5)	Internal
2b	1	fraction)		

#### Derived No Effect Level (DNEL)

Substance name	End Use	Exposure routes	Potential health ef- fects	Value
Disodium hy- drogenorthophos- phate	Workers	Inhalation	Long-term systemic effects	4.07 mg/m3
	Consumers	Inhalation	Long-term systemic effects	3.04 mg/m3

#### **Predicted No Effect Concentration (PNEC)**

Substance name	Environmental Compartment	Value
Disodium hydrogenorthophos-	Fresh water	0.05 mg/l
phate		
	Marine water	0.005 mg/l
	Intermittent use/release	0.5 mg/l
	Sewage treatment plant	50 mg/l

#### 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	:	V
		S

Wear the following personal protective equipment: Safety goggles Equipment should conform to BS EN 166



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Hand protection					
Ma	aterial	: Chemical-resis	stant gloves		
Remarks		on the concent stance and spe determined for applications, w chemicals of th	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 appropr sistance data a tial. Skin contact m	Select appropriate protective clothing based on chemical re- sistance data and an assessment of the local exposure poten- tial. Skin contact must be avoided by using impervious protective clothing (gloves, aprons, boots, etc).		
Respi	ratory protection	: If adequate loc sure assessme ommended gu	<ul> <li>If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.</li> <li>Equipment should conform to BS EN 143</li> </ul>		
Filt	ter type	: Particulates ty			

#### **SECTION 9: Physical and chemical properties**

#### 9.1 Information on basic physical and chemical properties

Appearance Colour Odour Odour Threshold	:	powder White to light yellow No data available No data available
рН	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling	:	No data available
range Flash point	:	No data available
Evaporation rate	:	No data available
Flammability (solid, gas)	:	May form explosive dust-air mixture during processing, han- dling or other means.
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapour pressure	:	No data available

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	Relative vapour density		:	No data available	e
	Density	/	:	1 g/cm <sup>3</sup>	
	Partitio octano	ter solubility n coefficient: n-	:	No data available No data available No data available	e
	-	position temperature	:	No data available	
		cosity, dynamic	:	No data available	
		cosity, kinematic ive properties	:	No data available Not explosive	e
	Oxidizing properties		:	The substance o	or mixture is not classified as oxidizing.
		nformation		<b>N</b> I 17 111	
		ability (liquids)	:	No data available	-
	Particle	ılar weight ə size	:	No data available No data available	-

#### **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					
Conditions to avoid :	Heat, flames and sparks. Avoid dust formation.				
10.5 Incompatible materials					
Materials to avoid	Oxidizing agents				

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#### 10.6 Hazardous decomposition products

No hazardous decomposition products are known.

#### **SECTION 11: Toxicological information**

<b>11.1 Information on toxicologic</b> Information on likely routes o exposure						
Acute toxicity Not classified based on avail	able	information.				
Components:						
Peginterferon Alfa-2b:						
Acute toxicity (other routes or administration)	f:	LD50 (Rat): > 20.1 mg/kg Application Route: Intravenous				
		LD50 (Monkey): > 9.8 mg/kg				
Sucrose: Acute oral toxicity	:	LD50 (Rat): 29,700 mg/kg				
Skin corrosion/irritation Not classified based on avail	able	information.				
Components:						
<b>Peginterferon Alfa-2b:</b> Species Result	:	Rabbit Mild skin irritation				
Serious eye damage/eye ir	ritati	on				
Not classified based on avail						
Components:						
<b>Peginterferon Alfa-2b:</b> Species Result	:	Rabbit Mild eye irritation				
Respiratory or skin sensiti	satio	n				
Skin sensitisation Not classified based on avail	<b>Skin sensitisation</b> Not classified based on available information.					
Respiratory sensitisation	Respiratory sensitisation					

Not classified based on available information.

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	a <b>cell mutagenicity</b> lassified based on avail	able	information.	
<u>Com</u>	oonents:			
Pegir	nterferon Alfa-2b:			
Geno	toxicity in vitro	:	Test Type: reve Result: negative	rse mutation assay
				mosomal aberration Iman lymphocytes
Geno	toxicity in vivo	:	Test Type: In viv Species: Mouse Result: negative	
Sucro	ose:			
	toxicity in vitro	:	Test Type: In vit Result: negative	ro mammalian cell gene mutation test
	nogenicity lassified based on avail	able	information.	
-	oductive toxicity damage fertility. May da	amag	e the unborn child	d.
<u>Com</u>	oonents:			
Pegir	nterferon Alfa-2b:			
Effect	ts on fertility	:	Species: Monke	
			Dose: 0.35 millig	te: Subcutaneous gram per kilogram ct 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.
STOT	- single exposure			
Not c	lassified based on avail	able	information.	
	repeated exposure lassified based on avail	able	information.	
Com	oonents:			
-	nterferon Alfa-2b: et Organs	:		tract, Immune system, Cardio-vascular sys- system, Central nervous system, Liver, Res-

piratory Tract, Eye

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Asse	essment	: Causes damage exposure.	e to organs through prolonged or repeated
Repe	eated dose toxicity		
<u>Com</u>	ponents:		
Spec NOA Appli Expc Spec NOA Appli	EL ication Route osure time cies EL ication Route osure time	<ul> <li>Mouse</li> <li>0.0038 mg/kg</li> <li>Subcutaneous</li> <li>9 d</li> <li>Rat</li> <li>0.0042 mg/kg</li> <li>Subcutaneous</li> <li>30 d</li> <li>Monkey</li> </ul>	
LOAI Appli Expo		: 0.12 mg/kg : Subcutaneous : 30 d	arrow, Immune system
	EL	<ul> <li>Monkey</li> <li>0.015 mg/kg</li> <li>0.077 mg/kg</li> <li>3 Months</li> <li>Respiratory Tra system, Bone m</li> </ul>	ct, Cardio-vascular system, Central nervous narrow

#### Aspiration toxicity

Not classified based on available information.

#### Experience with human exposure

#### **Components:**

Peginterferon Alfa-2b:

Inhalation

Symptoms: flu-like symptoms, Gastrointestinal disturbance, mental depression, tingling

#### **SECTION 12: Ecological information**

#### 12.1 Toxicity

Components:

Peginterferon Alfa-2b:

#### Ecotoxicology Assessment

Acute aquatic toxicity : No data available

:

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Chro	nic aquatic toxicity	:	No data available	
12.2 Pers	istence and degradabi	ility		
Com	ponents:			
-	nterferon Alfa-2b: egradability	:	Result: Readily b Biodegradation: Exposure time: 2 Method: OECD T	63 %
12.3 Bioa	ccumulative potential			
Com	ponents:			
	<b>ose:</b> ion coefficient: n- ol/water	:	Pow: < 1	
	<b>lity in soil</b> ata available			
12.5 Resu	llts of PBT and vPvB a	isse	ssment	
Prod Asse	<u>uct:</u> ssment	:	to be either persis	nixture contains no components considered stent, bioaccumulative and toxic (PBT), or nd very bioaccumulative (vPvB) at levels of
12.6 Othe	r adverse effects			
<u>Prod</u> Endo tial	uct: crine disrupting poten-	:	ered to have end	nixture does not contain components consid- ocrine disrupting properties for environment REACH Article 57(f).
SECTION	13: Disposal consi	der	ations	
13.1 Wast	e treatment methods			
Produ	uct	:	According to the are not product s Waste codes sho discussion with th	ordance with local regulations. European Waste Catalogue, Waste Codes pecific, but application specific. buld be assigned by the user, preferably in the waste disposal authorities.

#### **SAFETY DATA SHEET** According to REACH Regulation (EC) No 1907/2006, as amended by



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#### **SECTION 14: Transport information**

#### 14.1 UN number

	ADN	:	Not regulated as a dangerous good
	ADR	:	Not regulated as a dangerous good
I	RID	:	Not regulated as a dangerous good
I	IMDG	:	Not regulated as a dangerous good
I	ΙΑΤΑ	:	Not regulated as a dangerous good
14.2	UN proper shipping name		
1	ADN	:	Not regulated as a dangerous good
	ADR	:	Not regulated as a dangerous good
I	RID	:	Not regulated as a dangerous good
I	IMDG	:	Not regulated as a dangerous good
I	ΙΑΤΑ	:	Not regulated as a dangerous good
14.3	Transport hazard class(es)		
	ADN	:	Not regulated as a dangerous good
	ADR	:	Not regulated as a dangerous good
I	RID	:	Not regulated as a dangerous good
I	IMDG	:	Not regulated as a dangerous good
I	ΙΑΤΑ	:	Not regulated as a dangerous good
14.4	Packing group		
1	ADN	:	Not regulated as a dangerous good
	ADR	:	Not regulated as a dangerous good
I	RID	:	Not regulated as a dangerous good
I	IMDG	:	Not regulated as a dangerous good
I	IATA (Cargo)	:	Not regulated as a dangerous good
I	IATA (Passenger)	:	Not regulated as a dangerous good
14.5	Environmental hazards		

Not regulated as a dangerous good

#### 14.6 Special precautions for user

Not applicable

# **14.7 Transport in bulk according to Annex II of Marpol and the IBC Code**Remarks: Not applicable for product as supplied.



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#### **SECTION 15: Regulatory information**

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

Relevant EU provisions transposed through retained EU law

Not applicable
Not applicable
Not applicable
<b>NI</b> / P II
Not applicable
Not applicable
Not applicable
H)
1)

Not applicable

#### Other regulations:

Take note of The Management of Health and Safety at Work Regulations 1999 (requirements relating to new and expectant mothers at work contained in Regulation 16 to 18) and of the Pregnant Workers Directive 92/85/EEC.

Take note of The Management of Health and Safety at Work Regulations 1999 (requirements relating to protection of young people at work contained in Regulation 19) and of Directive 94/33/EC on the protection of young people at work.

#### 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.

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#### Full text of other abbreviations

Repr. STOT RE GB EH40 GB EH40 / TWA	:	Reproductive toxicity Specific target organ toxicity - repeated exposure UK. EH40 WEL - Workplace Exposure Limits Long-term exposure limit (8-hour TWA reference period)
GB EH40 / TWA	-	Long-term exposure limit (8-hour TWA reference period)
GB EH40 / STEL	:	Short-term exposure limit (15-minute reference period)

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 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 carrving 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 : 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/

#### Classification of the mixture:

Repr. 1B

H360FD

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



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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.

GB / EN