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

	Product identifier		
	Trade name	:	Interferon Alfa-2b Solid Formulation
		_	
1.2	Relevant identified uses of t	he s	ubstance 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	saf	ety data sheet
	Company		MSD
		•	1013D
	•••••••	·	Piercetown
		·	
	Telephone	:	Piercetown

## 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
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Specific target organ toxicity - repeated exposure, Category 2

### 2.2 Label elements

H360FD: May damage fertility. May damage the unborn child. H373: May cause damage to organs through prolonged or repeated exposure.

Labelling (REGULATION	(EC) No 1272/2008)
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Hazard pictograms : Signal word : Danger Hazard statements : H360FD May damage fertility. May damage the unborn according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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		H373	child. May cause damage to organs through prolonged or repeated exposure.
Preca	utionary statements	Prevention	
	-	P201	Obtain special instructions before use.
		P260 P280	Do not breathe dust. Wear protective gloves/ protective clothing/ eye protection/ face protection.
		Response:	
		P308 + P31	3 IF exposed or concerned: Get medical advice/ attention.
		Storage:	
		P405	Store locked up.

### Hazardous components which must be listed on the label:

Interferon 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. May form explosive dust-air mixture during processing, handling or other means.

## **SECTION 3: Composition/information on ingredients**

#### 3.2 Mixtures

#### Components

components		2	
Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Interferon alfa-2b	98530-12-2	Skin Irrit. 2; H315 Repr. 1B; H360FD STOT RE 2; H373 (Blood, Bone mar- row)  specific concentration	>= 1 - < 10



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			limit Repr. 1B; H360FD >= 0.001 % STOT RE 2; H373 >= 0.001 %

For explanation of abbreviations see section 16.

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

4.1 Description of first aid meas	ires			
General advice	<ul> <li>In the case of accident or if you feel unwell, seek medical a vice immediately.</li> <li>When symptoms persist or in all cases of doubt seek medi 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 plenty of wa 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>	ter.		
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 a	4.2 Most important symptoms and effects, both acute and delayed			
Risks	: May damage fertility. May damage the unborn child. May cause damage to organs through prolonged or repeat exposure.	ed		
	Dust contact with the eyes can lead to mechanical irritation	۱.		
4.3 Indication of any immediate medical attention and special treatment needed				
Treatment	: Treat symptomatically and supportively.			



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## **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.

## 5.2 Special hazards arising from the substance or mixture

5.2 Special nazards arising from	the	substance of 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	:	Carbon oxides Nitrogen oxides (NOx) Metal oxides Phosphorus compounds Oxides of phosphorus Carbon dioxide (CO2)
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	: 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	:	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.



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## 6.3 Methods and material for containment and cleaning up

Methods for cleaning up	<ul> <li>Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.</li> </ul>

## 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.
		The effective operation of a facility should include review of
		engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the
		use of administrative controls.



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7.2 Condi	tions for safe storage	, inc	luding any inco	mpatibilities			
Requirements for storage areas and containers		:	: Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular nationa regulations.				
Advic	e on common storage	:	<ul> <li>Do not store with the following product types: Strong oxidizing agents Self-reactive substances and mixtures Organic peroxides Explosives Gases</li> </ul>				
•	f <b>ic end use(s)</b> ific use(s)	:	No data availab	le			

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

## 8.1 Control parameters

dusts non-specific

## Occupational Exposure Limits

4 mg/m3 Value type (Form of exposure): OELV - 8 hrs (TWA) (Respirable dust) Basis: IE OEL

10 mg/m3 Value type (Form of exposure): OELV - 8 hrs (TWA) (inhalable dust) Basis: IE OEL

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Interferon alfa-2b	98530-12-2	TWA	0.2 μg/m3 (OEB 5)	Internal
		Wipe limit	2 µg/100 cm <sup>2</sup>	Internal

## Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006

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) according to Regulation (EC) No. 1907/2006

Substance name	Environmental Compartment	Value
Disodium hydrogenorthophos- phate	Fresh water	0.05 mg/l
	Marine water	0.005 mg/l



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		Intermittent u		0.5 mg/l
		Sewage trea	tment plant	50 mg/l

### 8.2 Exposure controls

### **Engineering measures**

Use closed processing systems or containment technologies to control at source (e.g., glove boxes/isolators) and to prevent leakage of compounds into the workplace.

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

No open handling permitted.

Totally enclosed processes and materials transport systems are required.

Operations require the use of appropriate containment technology designed to prevent leakage of compounds into the workplace.

#### Personal protective equipment

Eye/face protection	:	Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.	
Hand protection			
Material	:	Chemical-resistant gloves	
Remarks Skin and body protection	:	Consider double gloving. Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, dis- posable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.	
Respiratory protection Filter type	:	If adequate local exhaust ventilation is not available or expo- sure assessment demonstrates exposures outside the rec- ommended guidelines, use respiratory protection. Equipment should conform to I.S. EN 143 Particulates type (P)	
		、 /	

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

## 9.1 Information on basic physical and chemical properties

Physical state	:	powder
Colour	:	White to light yellow
Odour	:	No data available
Odour Threshold	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling	:	No data available



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	range						
	Flammability (solid, gas)		:	: May form explosive dust-air mixture during processing, han- dling or other means.			
	Flamm	ability (liquids)	:	No data available	e		
	Upper explosion limit / Upper flammability limit			No data available	e		
		explosion limit / Lower ability limit	:	No data availabl	e		
	Flash <sub>l</sub>	point	:	Not applicable			
	Auto-iç	gnition temperature	:	No data available	e		
	Decom	position temperature	:	No data available	e		
	рН		:	No data availabl	e		
	Viscos Vis	ity cosity, kinematic	:	Not applicable			
		lity(ies) ter solubility	÷	No data available	9		
		on coefficient: n- I/water	:	Not applicable			
	Vapou	r pressure	:	Not applicable			
	Relativ	e density	:	No data available	e		
	Densit	У	:	No data availabl	e		
	Relativ	ve vapour density	:	Not applicable			
		e characteristics ticle size	:	No data availabl	e		
9.2		nformation					
	Explos		:	Not explosive			
		ng properties	:		r mixture is not classified as oxidizing.		
	Evapo	ration rate	:	Not applicable			



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## **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	<ul> <li>May form explosive dust-air mixture during processing, han- dling or other means.</li> <li>Can react with strong oxidizing agents.</li> </ul>
10.4 Conditions to avoid	
Conditions to avoid	: Heat, flames and sparks.

Conditions to avoid	Heat, flames and spark
	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

Information on likely routes of	:	Inhalation
exposure		Skin contact
		Ingestion
		Eye contact

#### Acute toxicity

Not classified based on available information.

#### Skin corrosion/irritation

Not classified based on available information.

### **Components:**

#### Interferon alfa-2b:

Species	:	Rat
Result	:	Skin irritation

## Serious eye damage/eye irritation

Not classified based on available information.

## **Components:**

### Interferon alfa-2b:

Species	:	Rabbit
Remarks	:	slight irritation



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### 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:**

#### Interferon alfa-2b:

Genotoxicity in vitro :		Test Type: Chromosome aberration test in vitro Result: negative
		Test Type: Bacterial reverse mutation assay (AMES) Result: negative
Genotoxicity in vivo	:	Test Type: Micronucleus test Species: Mouse Result: negative Remarks: Based on data from similar materials

### Carcinogenicity

Not classified based on available information.

## Reproductive toxicity

May damage fertility. May damage the unborn child.

#### **Components:**

## Interferon alfa-2b:

Effects on fertility	:	Test Type: Fertility/early embryonic development Species: Monkey Fertility: LOAEL: 3.8 μg/kg Result: menstrual irregularities Remarks: Abortion
Effects on foetal develop- ment	:	Test Type: Fertility/early embryonic development Species: Monkey Developmental Toxicity: LOAEL: 3.8 µg/kg body weight Result: Embryolethal effects
Reproductive toxicity - As- sessment	:	May damage fertility. May damage the unborn child.

## STOT - single exposure

Not classified based on available information.

## STOT - repeated exposure

May cause damage to organs through prolonged or repeated exposure.

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<u>Components:</u> Interferon alfa-2b: Target Organs Assessment		: :	Blood, Bone marrow May cause damage to organs through prolonged or re exposure.		
	Repea	ted dose toxicity			
	<u>Comp</u>	onents:			
	Specie NOAE Applica	L ation Route ure time		Monkey 0.095 mg/kg Intramuscular 1 Months No significant adv	erse effects were reported
		L ation Route ure time		Rat 0.38 mg/kg Subcutaneous 3 Months No significant adv	erse effects were reported
		L ation Route ure time	:	Mouse 0.076 mg/kg Intraperitoneal 9 d No significant adv	erse effects were reported
	Expos	- ation Route ure time Organs		Monkey 0.38 mg/kg Intramuscular 3 Months Blood, Bone marr Significant toxicity	ow v observed in testing

## Aspiration toxicity

Not classified based on available information.

## 11.2 Information on other hazards

#### **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.



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Expe	rience with human e	xposure	
Com	ponents:		
Interf	feron alfa-2b:		
Skin	contact	: Symptoms: Th toms, Fever, c	e most common side effects are:, flu-like symp- hills, Fatigue
SECTION	N 12: Ecological inf	ormation	
12.1 Toxic	city		
No da	ata available		
12.2 Persi	istence and degrada	bility	
No da	ata available		

#### 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

_		-			
D	ro	d		<b>^</b> +	
	ιv	u	uv	-	

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	Wast	e treatment me	ethods

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-

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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		
IMDG	:	Not regulated as a dangerous good		
ΙΑΤΑ	:	Not regulated as a dangerous good		
14.2 UN proper shipping name				
ADN	:	Not regulated as a dangerous good		
ADR	:	Not regulated as a dangerous good		
RID	:	Not regulated as a dangerous good		
IMDG	:	Not regulated as a dangerous good		
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		
RID	:	Not regulated as a dangerous good		
IMDG	:	Not regulated as a dangerous good		
ΙΑΤΑ	:	Not regulated as a dangerous good		
14.4 Packing group				
ADN	:	Not regulated as a dangerous good		
ADR	:	Not regulated as a dangerous good		
RID	:	Not regulated as a dangerous good		
IMDG	:	Not regulated as a dangerous good		
IATA (Cargo)	:	Not regulated as a dangerous good		
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 Maritime transport in bulk according to IMO instruments

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII)	:	Not applicable
REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59).	:	Not applicable
Regulation (EC) on substances that deplete the ozone layer	:	Not applicable
Regulation (EU) 2019/1021 on persistent organic pollu- tants (recast)	:	Not applicable
Regulation (EU) No 649/2012 of the European Parlia- ment and the Council concerning the export and import of dangerous chemicals	:	Not applicable
REACH - List of substances subject to authorisation (Annex XIV)	:	Not applicable
Seveso III: Directive 2012/18/EU of the European Parliar	nent	and of the Council on t

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:

Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.

Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

#### 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

Causes skin irritation. May damage fertility. May damage the unborn child. May cause damage to organs through prolonged or repeated
exposure.

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#### Full text of other abbreviations

Repr. Skin Irrit. STOT RE IE OEL	:	Reproductive toxicity Skin irritation Specific target organ toxicity - repeated exposure Ireland. List of Chemical Agents and Carcinogens with Occu- pational Exposure Limit Values - Code of Practice, Schedule 1 and 2
IE OEL / OELV - 8 hrs (TWA)	:	

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 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; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations: vPvB - Verv 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/

#### Classification of the mixture:

Classification of the mixtur	Classification procedure:	
Repr. 1B	H360FD	Calculation method
STOT RE 2	H373	Calculation method



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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.

IE / EN