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

	Product identifier Trade name	:	Peginterferon Alfa-2b Redipen Formulation
1.2 F	Relevant identified uses of th	ne 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	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 c 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	I3 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

For explanation of abbreviations see section 16.

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



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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.</li> <li>Get medical attention.</li> <li>Rinse mouth thoroughly with water.</li> </ul>		
4.2 Most important symptoms and	l 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

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	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
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. If spillage enters rivers or watercourses, inform the Environ- ment Agency (emergency telephone number 0800 807060).
6.3 Methods and material for con	ntai	nment 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. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

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### 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, including 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 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	:	Wear the following personal protective equipment: Safety goggles Equipment should conform to BS 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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Filter ty	vpe	Equipment shouts a Particulates type	lld conform to BS EN 143 ∋ (P)	

# SECTION 9: Physical and chemical properties

# 9.1 Information on basic physical and chemical properties

Appearance Colour Odour Odour Threshold	:	powder off-white No data available No data available
рН	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
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
Relative vapour density	:	No data available
Relative density	:	No data available
Solubility(ies) Water solubility Partition coefficient: n- octanol/water Auto-ignition temperature	: :	soluble No data available No data available
Decomposition temperature	:	No data available
Viscosity Viscosity, kinematic	:	No data available
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.

## 9.2 Other information

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Fla	ammability (liquids)	: N	lo data available	9
Мо	blecular weight	: N	lo data available	
Pa	rticle size	: N	lo 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	<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. 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 toxicological effects

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

## Acute toxicity

Not classified based on available information.

#### **Components:**

# Peginterferon Alfa-2b:

Acute toxicity (other routes of :	LD50 (Rat): > 20.1 mg/kg
administration)	Application Route: Intravenous

LD50 (Monkey): > 9.8 mg/kg

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# Skin corrosion/irritation

Not classified based on available information.

## Components:

## Peginterferon Alfa-2b:

Species	:	Rabbit
Result	:	Mild skin irritation

# Serious eye damage/eye irritation

Not classified based on available information.

#### Components:

#### Peginterferon Alfa-2b:

Species	:	Rabbit
Result	:	Mild eye irritation

#### Respiratory or skin sensitisation

#### Skin sensitisation

Not classified based on available information.

#### **Respiratory sensitisation**

Not classified based on available information.

#### Germ cell mutagenicity

Not classified based on available information.

#### **Components:**

#### Peginterferon Alfa-2b:

Genotoxicity in vitro		Test Type: reverse mutation assay Result: negative		
		Test Type: Chromosomal aberration Test system: Human lymphocytes Result: negative		
Genotoxicity in vivo	:	Test Type: In vivo micronucleus test Species: Mouse Result: negative		

## 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



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			Species: Monkey Application Route Dose: 0.35 milligr Symptoms: Effect	: Subcutaneous am per kilogram
	productive toxicity - As- sment	:	animal experimer	adverse effects on development, based on tts., Clear evidence of adverse effects on nd fertility, based on animal experiments.
	<b>DT - single exposure</b> classified based on availa	able	information.	
	<b>DT - repeated exposure</b> classified based on availa	able	information.	
<u>Co</u>	nponents:			
Peç	ginterferon Alfa-2b:			
Tar	get Organs	:		act, Immune system, Cardio-vascular sys- /stem, Central nervous system, Liver, Res- e
Ass	essment	:		o organs through prolonged or repeated
Rej	peated dose toxicity			
<u>Co</u>	nponents:			
Peç	ginterferon Alfa-2b:			
NO Apr	ecies AEL blication Route bosure time	:	Mouse 0.0038 mg/kg Subcutaneous 9 d	
NO Apr	ecies AEL blication Route bosure time	:	Rat 0.0042 mg/kg Subcutaneous 30 d	
LÖ/ App Exp	ecies AEL blication Route bosure time get Organs	:	Monkey 0.12 mg/kg Subcutaneous 30 d Blood, Bone marr	ow, Immune system
NÖ LO/ Exp	ecies AEL AEL oosure time get Organs		Monkey 0.015 mg/kg 0.077 mg/kg 3 Months Respiratory Tract system, Bone ma	, Cardio-vascular system, Central nervous rrow

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#### UK REACH Regulations SI 2019/758

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# 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		
Chronic aquatic toxicity	:	No data available		

## 12.2 Persistence and degradability

## **Components:**

## Peginterferon Alfa-2b:

Biodegradability	:	Result: Readily biodegradable. Biodegradation: 63 %
		Exposure time: 28 d
		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 Other adverse effects

## Product:

Endocrine disrupting poten- : This substance/mixture does not contain components consid-



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tial			docrine disrupting properties for environment K REACH Article 57(f).

# **SECTION 13: Disposal considerations**

13.1 Waste treatment methods	
Product	<ul> <li>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.</li> </ul>
Contaminated packaging	<ul> <li>Empty containers should be taken to an approved waste han- dling site for recycling or disposal.</li> <li>If not otherwise specified: Dispose of as unused product.</li> </ul>

# **SECTION 14: Transport information**

# 14.1 UN 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



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RID		:	Ū	a dangerous good a dangerous good
IATA	(Cargo) (Passenger)	:	Not regulated as	a dangerous good a dangerous good
14.5 Envir	conmental hazards	ıs go	0	
	ial precautions for us pplicable	ser		

# 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

UK REACH List of restrictions (Annex 17)	:	Not applicable
UK REACH Candidate list of substances of very high concern (SVHC) for Authorisation	:	Not applicable
The Persistent Organic Pollutants Regulations (retained Regulation (EU) 2019/1021 as amended for Great Brit-	:	Not applicable
ain) Regulation (EC) on substances that deplete the ozone	:	Not applicable
layer UK REACH List of substances subject to authorisation	:	Not applicable
(Annex XIV) GB Export and import of hazardous chemicals - Prior		Not applicable
Informed Consent (PIC) Regulation	•	
Control of Major Accident Hazards Regulations 2015 (CC Not applicable	IVIA	ιΠ <i>)</i>

## 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

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#### 15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

<b>,</b>			
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-Statemer	its		
H360FD H372	<ul> <li>May damage fertility. May damage the unborn child.</li> <li>Causes damage to organs through prolonged or repeated exposure.</li> </ul>		
Full text of other abbre	viations		
Repr. STOT RE GB EH40 GB EH40 / TWA	<ul> <li>Reproductive toxicity</li> <li>Specific target organ toxicity - repeated exposure</li> <li>UK. EH40 WEL - Workplace Exposure Limits</li> <li>Long-term exposure limit (8-hour TWA reference period)</li> </ul>		

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; TSCA - Toxic Substances Control Act (United States); UN

#### SAFETY DATA SHEET According to REACH Regulation (EC) No 190

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H360FD

- United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

# Further information

compile the Safety Data eC	ternal technical data, data from raw material SDSs, OECD Chem Portal search results and European Chemicals Agen- r, http://echa.europa.eu/
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Repr. 1B

# 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.

GB / EN