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Peginterferon Alfa-2b Powder Formulation

3.1 26.09.2023 20526-00023 Date of first issue: 09.10.2014	Version	Revision Date:	SDS Number:	Date of last issue: 20.03.2023
	3.1	26.09.2023	20526-00023	Date of first issue: 09.10.2014

1. PRODUCT AND COMPANY IDENTIFICATION

Product name	:	Peginterferon Alfa-2b Powder Formulation				
Manufacturer or supplier's details						
Company	:	MSD				
Address	:	Briahnager - Off Pune Nagar Road Wagholi - Pune - India 412 207				
Telephone	:	+1-908-740-4000				
Emergency telephone number	:	+1-908-423-6000				
E-mail address	:	EHSDATASTEWARD@msd.com				
Recommended use of the ch	em	ical and restrictions on use				
Recommended use	:	Pharmaceutical				
Restrictions on use	:	Not applicable				

2. HAZARDS IDENTIFICATION

Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

Classification

Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

GHS Classification		
Reproductive toxicity	:	Category 1B
GHS label elements		
Hazard pictograms	:	
Signal word	:	Danger
Hazard statements	:	H360FD May damage fertility. May damage the unborn child.
Precautionary statements	:	Prevention:
		P203 Obtain, read and follow all safety instructions before use. P280 Wear protective gloves/ protective clothing/ eye protec- tion/ face protection.
		Response:
		P318 IF exposed or concerned, get medical advice.

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Storage:

P405 Store locked up.

Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards which do not result in classification

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.

Mixture

:

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Sucrose	57-50-1	>= 90 - <= 100
Peginterferon Alfa-2b	215647-85-1	>= 0.3 - < 1

4. FIRST AID MEASURES

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.
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.
Most important symptoms and effects, both acute and delayed	:	May damage fertility. May damage the unborn child. Contact with dust can cause mechanical irritation or drying of the skin.
Protection of first-aiders	:	Dust contact with the eyes can lead to mechanical irritation. 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).
Notes to physician	:	Treat symptomatically and supportively.

5. FIREFIGHTING MEASURES

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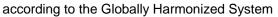
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Unsuit media	e extinguishing media able extinguishing	:	Water spray Alcohol-resistant f Carbon dioxide (C Dry chemical None known.	:02)
fighting	c hazards during fire-	•	concentrations, ar potential dust exp	dust; fine dust dispersed in air in sufficient nd in the presence of an ignition source is a losion hazard. pustion products may be a hazard to health.
Hazaro ucts	lous combustion prod-	:	Metal oxides Phosphorus comp Oxides of phosph Carbon oxides	
Specifi ods	c extinguishing meth-	:	cumstances and t Use water spray to	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
	l protective equipment fighters	:		e, wear self-contained breathing apparatus. ective equipment.
6. ACCIDENTAL RELEASE MEASURES				
tive eq	al precautions, protec- uipment and emer- procedures	:		ective equipment. ing advice (see section 7) and personal pro- recommendations (see section 8).
Enviro	nmental precautions	:	Retain and dispos	akage or spillage if safe to do so. e of contaminated wash water. should be advised if significant spillages
	ds and materials for ment and cleaning up	:	tainer for disposal Avoid dispersal of with compressed Dust deposits sho es, as these may leased into the atr Local or national r posal of this mate employed in the c mine which regula Sections 13 and 1	dust in the air (i.e., clearing dust surfaces

7. HANDLING AND STORAGE

Technical measures

: Static electricity may accumulate and ignite suspended dust





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	cal/Total ventilation lvice on safe handling	 and bonding, or If sufficient ventiventilation. Do not get on sk Do not breathe or Do not swallow. Avoid contact with Handle in accord practice, based or sessment Keep container to Minimize dust get Keep container or Keep away from Take precaution 	te precautions, such as electrical grounding inert atmospheres. lation is unavailable, use with local exhaust tin or clothing. dust. ith eyes. dance with good industrial hygiene and safety on the results of the workplace exposure as-
Co	onditions for safe storage	environment. : Keep in properly Store locked up. Keep tightly clos	
Ma	aterials to avoid	Store in accorda	nce with the particular national regulations. n the following product types:

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis
Sucrose	57-50-1	TWA	10 mg/m3	ACGIH
Peginterferon Alfa-2b	215647-85-1	TWA (inhal- able fraction)	0.2 µg/m3 (OEB 5)	Internal

Engineering measures :	Minimize workplace exposure concentrations. Apply measures to prevent dust explosions. Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are de- signed 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	t
Respiratory protection :	If adequate local exhaust ventilation is not available or expo- sure assessment demonstrates exposures outside the rec- ommended guidelines, use respiratory protection.
Filter type : Hand protection	Particulates type

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N	laterial	: Chemical-resistant gloves			
Remarks		on the conce stance and s determined fo applications, chemicals of	es to protect hands against chemicals depending ntration and quantity of the hazardous sub- pecific to place of work. Breakthrough time is not or the product. Change gloves often! For special we recommend clarifying the resistance to the aforementioned protective gloves with the acturer. Wash hands before breaks and at the av.		
Eye	protection	: Wear the following personal protective equipment: Safety goggles			
Skin	and body protection	: Select appropriation : Select appropriation : Sistance data tial. Skin contact	priate protective clothing based on chemical re- and an assessment of the local exposure poten- must be avoided by using impervious protective res, aprons, boots, etc).		
Hygi	ene measures	: If exposure to flushing syste place. When using o	b chemical is likely during typical use, provide eyeems and safety showers close to the working do not eat, drink or smoke. hinated clothing before re-use.		

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	powder
Colour	:	White to light yellow
Odour	:	No data available
Odour Threshold	:	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.
Flammability (liquids)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available

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	Vapou	pressure	:	No data available	2
	Relative vapour density		:	No data available	9
	Density	/	:	1 g/cm ³	
	Solubility(ies)				
	Wat	er solubility	:	No data available	9
	Partitio octano	n coefficient: n-	:	No data available	9
		nition temperature	:	No data available	9
	Decom	position temperature	:	No data available	9
	Viscosi Visc	ty cosity, dynamic	:	No data available	e
	Viso	cosity, kinematic	:	No data available	9
	Explos	ive properties	:	Not explosive	
	Oxidizi	ng properties	:	The substance o	r mixture is not classified as oxidizing.
	Molecu	ılar weight	:	No data available	9
	Particle	e size	:	No data available	e

10. STABILITY AND REACTIVITY

Reactivity Chemical stability Possibility of hazardous reac- tions	: :	Not classified as a reactivity hazard. Stable under normal conditions. May form explosive dust-air mixture during processing, han- dling or other means. Can react with strong oxidizing agents.
Conditions to avoid	:	Heat, flames and sparks. Avoid dust formation.
Incompatible materials Hazardous decomposition products	:	

11. TOXICOLOGICAL INFORMATION

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

Acute toxicity

Not classified based on available information.

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rsion I	Revision Date: 26.09.2023		9S Number: 526-00023	Date of last issue: 20.03.2023 Date of first issue: 09.10.2014
Comp	enente.			
	onents:			
Sucro	se: oral toxicity	:	LD50 (Rat): 29,7	100 ma/ka
Acule		·	LD30 (Rat). 29,7	00 mg/kg
Pegin	terferon Alfa-2b:			
	toxicity (other routes of istration)	:	LD50 (Rat): > 20 Application Rout	
			LD50 (Monkey):	> 9.8 mg/kg
	corrosion/irritation assified based on availa	able	information.	
<u>Comp</u>	onents:			
Pegin	terferon Alfa-2b:			
Specie Result		:	Rabbit Mild skin irritatio	n
	us eye damage/eye irr assified based on availa			
<u>Comp</u>	onents:			
Pegin	terferon Alfa-2b:			
Specie Result		:	Rabbit Mild eye irritatior	n
		-		
Respi	ratory or skin sensitis	atio	n	
	ensitisation assified based on availa	able	information.	
Respi	ratory sensitisation			
Not cla	assified based on availa	able	information.	
	cell mutagenicity			
	assified based on availa	able	information.	
Comp	onents:			
Sucro			Toot Tumor las 1	ro mommolion cell rese mutation to t
Genot	oxicity in vitro	:	Result: negative	ro mammalian cell gene mutation test
			-	
-	terferon Alfa-2b:		Toot Turoot route	
Genot	oxicity in vitro	:	Result: negative	se mutation assay

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sion	Revision Date: 26.09.2023		S Number: 526-00023	Date of last issue: 20.03.2023 Date of first issue: 09.10.2014
			Result: negati	ve
Geno	toxicity in vivo		Test Type: In Species: Mou Result: negati	
	inogenicity lassified based on avai	ilable i	nformation.	
Repr	oductive toxicity			
	damage fertility. May da	amage	e the unborn ch	nild.
<u>Com</u>	ponents:			
-	nterferon Alfa-2b:		Tast Tast - E	
Filec	ts on fertility		Test Type: Fe Species: Mon	rtility/early embryonic development key, female
			Application Ro	oute: Subcutaneous
				lligram per kilogram fect on estrous cycle
sessr STOT	Γ - single exposure		animal experir sexual functio	ments., Clear evidence of adverse effects or
STOT Not cl	nent	lable i	animal experir sexual functio nformation.	ments., Clear evidence of adverse effects on
SESSI STOT Not c STOT Not c	nent Γ - single exposure lassified based on avai Γ - repeated exposure	lable i	animal experir sexual functio nformation.	ments., Clear evidence of adverse effects on
STOT Not c STOT Not c <u>Com</u> Pegir	nent C - single exposure lassified based on avail C - repeated exposure lassified based on avail ponents: nterferon Alfa-2b:	ilable i Iable i	animal experir sexual functio nformation. nformation.	nents., Clear evidence of adverse effects on n and fertility, based on animal experiments.
STOT Not c STOT Not c <u>Com</u> Pegir	nent Γ - single exposure lassified based on avai Γ - repeated exposure lassified based on avai ponents:	ilable i ilable i	animal experir sexual functio nformation. nformation. Gastrointestin tem, Endocrin	nents., Clear evidence of adverse effects on n and fertility, based on animal experiments. al tract, Immune system, Cardio-vascular sy e system, Central nervous system, Liver, Re
SESSI STOT Not c STOT Not c Com Pegir Targe	nent C - single exposure lassified based on avail C - repeated exposure lassified based on avail ponents: nterferon Alfa-2b:	ilable i ilable i :	animal experir sexual functio nformation. nformation. Gastrointestin tem, Endocrin piratory Tract,	nents., Clear evidence of adverse effects on n and fertility, based on animal experiments. al tract, Immune system, Cardio-vascular sy e system, Central nervous system, Liver, Re Eye
sessr STOI Not c STOI Not c Com Targe Asses	nent Γ - single exposure lassified based on avail Γ - repeated exposure lassified based on avail ponents: nterferon Alfa-2b: et Organs	ilable i ilable i :	animal experir sexual functio nformation. nformation. Gastrointestin tem, Endocrin piratory Tract, Causes dama	nents., Clear evidence of adverse effects on n and fertility, based on animal experiments. al tract, Immune system, Cardio-vascular sy e system, Central nervous system, Liver, Re
sessr STOI Not c STOI Not c Com Pegir Targe Asses Repe	nent F - single exposure lassified based on avail F - repeated exposure lassified based on avail ponents: hterferon Alfa-2b: et Organs ssment	ilable i ilable i :	animal experir sexual functio nformation. nformation. Gastrointestin tem, Endocrin piratory Tract, Causes dama	nents., Clear evidence of adverse effects on n and fertility, based on animal experiments. al tract, Immune system, Cardio-vascular sy e system, Central nervous system, Liver, Re Eye
sessr STOI Not c STOI Not c Com Targe Asses Repe <u>Com</u>	nent F - single exposure lassified based on avail F - repeated exposure lassified based on avail ponents: hterferon Alfa-2b: et Organs ssment ssment	ilable i ilable i :	animal experir sexual functio nformation. nformation. Gastrointestin tem, Endocrin piratory Tract, Causes dama	nents., Clear evidence of adverse effects on n and fertility, based on animal experiments. al tract, Immune system, Cardio-vascular sy e system, Central nervous system, Liver, Re Eye
sessr STOT Not c STOT Not c Comj Pegir Speci	nent F - single exposure lassified based on avail F - repeated exposure lassified based on avail ponents: nterferon Alfa-2b: et Organs ssment ssment rated dose toxicity ponents: nterferon Alfa-2b: ies	ilable i ilable i : :	animal experir sexual functio nformation. nformation. Gastrointestin tem, Endocrin piratory Tract, Causes dama exposure. Mouse	nents., Clear evidence of adverse effects on n and fertility, based on animal experiments. al tract, Immune system, Cardio-vascular sy e system, Central nervous system, Liver, Re Eye
sessr STOI Not c STOI Not c Com Targe Asses Repe Com Speci NOAE	nent F - single exposure lassified based on avail F - repeated exposure lassified based on avail ponents: hterferon Alfa-2b: exted dose toxicity ponents: hterferon Alfa-2b: ies EL	ilable i ilable i : :	animal experir sexual functio nformation. nformation. Gastrointestin tem, Endocrin piratory Tract, Causes dama exposure.	nents., Clear evidence of adverse effects on n and fertility, based on animal experiments. al tract, Immune system, Cardio-vascular sy e system, Central nervous system, Liver, Re Eye ge to organs through prolonged or repeated
sessr STOT Not c STOT Not c Com Pegir Targe Asses Repe <u>Com</u> Speci NOAE Applid	nent F - single exposure lassified based on avail F - repeated exposure lassified based on avail ponents: nterferon Alfa-2b: et Organs ssment ssment rated dose toxicity ponents: nterferon Alfa-2b: ies	ilable i ilable i : :	animal experir sexual functio nformation. nformation. Gastrointestin tem, Endocrin piratory Tract, Causes dama exposure. Mouse 0.0038 mg/kg	nents., Clear evidence of adverse effects on n and fertility, based on animal experiments. al tract, Immune system, Cardio-vascular sy e system, Central nervous system, Liver, Re Eye ge to organs through prolonged or repeated
sessr STOT Not c STOT Not c Com Pegir Targe Asses Repe Com NOAE Applic Expos Speci	nent F - single exposure lassified based on avail F - repeated exposure lassified based on avail ponents: hterferon Alfa-2b: et Organs ssment ssment rated dose toxicity ponents: hterferon Alfa-2b: ies EL cation Route sure time ies	ilable i ilable i : : :	animal experir sexual functio nformation. nformation. Gastrointestin tem, Endocrin piratory Tract, Causes dama exposure. Mouse 0.0038 mg/kg Subcutaneous 9 d Rat	nents., Clear evidence of adverse effects on n and fertility, based on animal experiments. al tract, Immune system, Cardio-vascular sy e system, Central nervous system, Liver, Re Eye ge to organs through prolonged or repeated
Sessr STOT Not c STOT Not c Com Targe Asses Repe Com Speci NOAE	nent F - single exposure lassified based on avail F - repeated exposure lassified based on avail ponents: hterferon Alfa-2b: et Organs ssment ssment rated dose toxicity ponents: hterferon Alfa-2b: ies EL cation Route sure time ies	ilable i ilable i : : : :	animal experir sexual functio nformation. nformation. Gastrointestin tem, Endocrin piratory Tract, Causes dama exposure. Mouse 0.0038 mg/kg Subcutaneous 9 d	ge to organs through prolonged or repeated

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Expos		: Monkey : 0.12 mg/kg : Subcutaneous : 30 d : Blood, Bone ma	arrow, Immune system

Species NOAEL	: Monkey : 0.015 mg/kg
LOAEL	: 0.077 mg/kg
Exposure time	: 3 Months
Target Organs	: Respiratory Tract, Cardio-vascular system, Central nervous system, Bone marrow

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

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Peginterferon Alfa-2b:

Ecotoxicology Assessment

Acute aquatic toxicity	:	No data available

Chronic aquatic toxicity : No data available

Persistence and degradability

Components:

Peginterferon Alfa-2b:

Biodegradability : Result: Readily biodegradable. Biodegradation: 63 % Exposure time: 28 d Method: OECD Test Guideline 301B

Bioaccumulative potential

Components:

Sucrose:

Partition coefficient: n- : Pow: < 1

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/water y in soil a available adverse effects a available AL CONSIDERATI al methods from residues hinated packaging PORT INFORMATION tional Regulations OG ulated as a dangero	 Do not dispose Dispose of in a Empty contain dling site for re If not otherwis 	e of waste into sewer. accordance with local regulations. hers should be taken to an approved waste han- ecycling or disposal. se specified: Dispose of as unused product.
a available adverse effects a available AL CONSIDERATI al methods from residues hinated packaging PORT INFORMATIC tional Regulations	 Do not dispose Dispose of in a Empty contain dling site for re If not otherwis 	accordance with local regulations. hers should be taken to an approved waste han- ecycling or disposal.
adverse effects a available AL CONSIDERATI al methods from residues hinated packaging PORT INFORMATIC tional Regulations	 Do not dispose Dispose of in a Empty contain dling site for re If not otherwis 	accordance with local regulations. hers should be taken to an approved waste han- ecycling or disposal.
a available AL CONSIDERATI al methods from residues hinated packaging PORT INFORMATIC tional Regulations	 Do not dispose Dispose of in a Empty contain dling site for re If not otherwis 	accordance with local regulations. hers should be taken to an approved waste han- ecycling or disposal.
AL CONSIDERATI al methods from residues hinated packaging PORT INFORMATIC tional Regulations	 Do not dispose Dispose of in a Empty contain dling site for re If not otherwis 	accordance with local regulations. hers should be taken to an approved waste han- ecycling or disposal.
al methods from residues hinated packaging PORT INFORMATIC tional Regulations	 Do not dispose Dispose of in a Empty contain dling site for re If not otherwis 	accordance with local regulations. hers should be taken to an approved waste han- ecycling or disposal.
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PORT INFORMATIO	: Empty contain dling site for re If not otherwis	ners should be taken to an approved waste han ecycling or disposal.
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tional Regulations)G	5	
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-		
ulated as a dallyell	Jua yuuu	
GR ulated as a dangero	ous good	
Code ulated as a dangero	ous good	
ort in bulk accordi	ing to IMO instrumer as supplied.	nts
I precautions for u		
ATORY INFORMAT	ΓΙΟΝ	
health and enviro	nmental regulations	/legislation specific for the substance or mix
mnononio et 16:	roduct are reported : not determine	-
inponents of this k		
inponents of this p	: not determine	bd
		nponents of this product are reported : not determine

16. OTHER INFORMATION

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	Furthe	r information			
	Sources of key data used to compile the Safety Data Sheet Date format Full text of other abbreviati		:		data, data from raw material SDSs, OECD arch results and European Chemicals Agen- ropa.eu/
			:	dd.mm.yyyy	
			ons		
	ACGIH		:	USA. ACGIH Thre	eshold Limit Values (TLV)
	ACGIH / TWA		:	8-hour, time-weig	hted average

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR -Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response: ERG - Emergency Response Guide: GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods: TECI - Thailand Existing Chemicals Inventory: TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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.