

Versio 2.7	on	Revision Date: 09.04.2021		S Number: 1076-00009	Date of last issue: 10.10.2020 Date of first issue: 19.07.2017	
Sectio	on 1: l	dentification				
Р	Product name			Betamethasone	Dintment Formulation	
N	Manufacturer or supplier's d			ls		
	Compa		:	Organon & Co.		
A	ddres	S	:	30 Hudson Street, 33nd floor Jersey City, New Jersey, U.S.A 07302		
Т	elepho	one	:	551-430-6000		
E	Emerge	ency telephone number	:	215-631-6999		
E	E-mail a	address	:	EHSSTEWARD	⊉organon.com	
R	Recom	mended use of the ch	nem	ical and restriction	ons on use	
R	Recom	mended use	:	Pharmaceutical		
Sectio	on 2: l	Hazard identification				
G	SHS C	lassification				
R	Reprod	luctive toxicity	:	Category 1B		
	Specific target organ toxicity - repeated exposure		:	Category 1 (Pitui gland, Blood, Ad	tary gland, Immune system, muscle, thymus renal gland)	
G	SHS la	bel elements				
Н	lazard	pictograms	:			
S	Signal	word	:	Danger		
Н	Hazard statements		:	H360D May damage the unborn child. H372 Causes damage to organs (Pituitary gland, Immune tem, muscle, thymus gland, Blood, Adrenal gland) through longed or repeated exposure.		
Ρ	Precau	tionary statements	:	P202 Do not han and understood. P260 Do not brea P264 Wash skin P270 Do not eat, P281 Use persor Response:	cial instructions before use. dle until all safety precautions have been read athe dust/ fume/ gas/ mist/ vapours/ spray. thoroughly after handling. drink or smoke when using this product. hal protective equipment as required. exposed or concerned: Get medical advice/	
					Superior of concerned. Get medical advice/	



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		attention.					
		Storage:					
		P405 Store loc	ked up.				
		Disposal:					
		P501 Dispose of contents/ container to an approved waste disposal plant.					
Other hazards which do not result in classification							
None	known.						
Section 3	Section 3: Composition/information on ingredients						
Subs	tance / Mixture	: Mixture					
Com	ponents						

Chemical name	CAS-No.	Concentration (% w/w)
Petrolatum	8009-03-8	>= 60 -<= 100
Paraffin oil	8012-95-1	< 10
betamethasone	378-44-9	>= 0.01 -< 0.3

Section 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	:	Flush eyes with water as a precaution. 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 the unborn child. Causes damage to organs through prolonged or repeated exposure.
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).
Notes to physician	:	Treat symptomatically and supportively.

Section 5: Fire-fighting measures

Suitable extinguishing	media
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: Water spray



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	Unsuitable extinguishing media Specific hazards during fire- fighting		:		CO2) In explosive mixtures with air. Dustion products may be a hazard to health.		
	Hazard ucts	lous combustion prod-	:	Carbon oxides			
	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.			
	Special protective equipment for firefighters Hazchem Code		:	In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment. 2Z			
Sec	Section 6: Accidental release me			ures			
	Personal precautions, protec- tive equipment and emer- gency procedures		:	Use personal protective equipment. Follow safe handling advice (see section 7) and personal p tective equipment recommendations (see section 8).			
	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.			
	Methods and materials for containment and cleaning up		:	tainer for disposal Local or national r posal of this mate employed in the c mine which regula Sections 13 and 1	um up spillage and collect in suitable con- regulations may apply to releases and dis- rial, as well as those materials and items leanup of releases. You will need to deter- ations are applicable. 5 of this SDS provide information regarding tional requirements.		
Sec	Section 7: Handling and storage						

Technical measures	: See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.	
Local/Total ventilation	: If sufficient ventilation is unavailable, use with local exhaust ventilation.	t
Advice on safe handling	 Do not get on skin or clothing. Do not breathe dust, fume, gas, mist, vapours or spray. Do not swallow. Avoid contact with eyes. Wash skin thoroughly after handling. Handle in accordance with good industrial hygiene and safe practice, based on the results of the workplace exposure as 	



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Hyg	ene measures	 Take care to preenvironment. If exposure to characteristic exposure to characteristic exposure to characteristic explace. When using do not wash contaminateristic effective op engineering con appropriate degrees. 	k or smoke when using this product. event spills, waste and minimize release to the memical is likely during typical use, provide eye is and safety showers close to the working not eat, drink or smoke. ated clothing before re-use. eration of a facility should include review of trols, proper personal protective equipment, owning and decontamination procedures, ne monitoring, medical surveillance and the
Con	ditions for safe storage	: Keep in properly Store locked up. Keep tightly close	v labelled containers.
Mate	erials to avoid		ance with the particular national regulations. h the following product types: agents

Section 8: Exposure controls/personal protection

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis	
Petrolatum	8009-03-8	WES-TWA (Mist)	5 mg/m3	NZ OEL	
	Further inforr vapour.	nation: Sampled	by a method that doe	s not collect	
		WES-STEL (Mist)	10 mg/m3	NZ OEL	
		TWA (Inhal- able particu- late matter)	5 mg/m3	ACGIH	
Paraffin oil	8012-95-1	WES-TWA (Mist)	5 mg/m3	NZ OEL	
		WES-STEL (Mist)	10 mg/m3	NZ OEL	
		TWA (Inhal- able particu- late matter)	5 mg/m3	ACGIH	
betamethasone	378-44-9	TWA	1 µg/m3 (OEB 4)	Internal	
	Further inforr	Further information: Skin			
		Wipe limit	10 µg/100 cm ²	Internal	

Components with workplace control parameters

Engineering measures

: Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., vacuum conveying from a closed system, packout head with inflatable seal from



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		ntainer, ventilated enclosure, etc.). Ig controls should be implemented by facility perated in accordance with GMP principles to cts, workers, and the environment. o open handling permitted. rocessing systems or containment technologies.					
Pers	onal protective equip	nent					
Respiratory protection		sure assessm	If adequate local exhaust ventilation is not available or expo- sure assessment demonstrates exposures outside the rec- ommended guidelines, use respiratory protection.				
	Iter type protection		: Combined particulates and organic vapour type				
M	aterial	: Chemical-res	istant gloves				
	emarks protection	If the work en mists or aeros Wear a faces	ble gloving. glasses with side shields or goggles. vironment or activity involves dusty conditions, sols, wear the appropriate goggles. hield or other full face protection if there is a lirect contact to the face with dusts, mists, or				
Skin	and body protection	: Work uniform Additional boot task being pe posable suits	or laboratory coat. dy garments should be used based upon the rformed (e.g., sleevelets, apron, gauntlets, dis-) to avoid exposed skin surfaces. ate degowning techniques to remove potentially clothing.				

Section 9: Physical and chemical properties

Appearance		ointment
Colour	:	No data available
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		> 93.3 °C
Evaporation rate		Not applicable
Flammability (solid, gas)		Not classified as a flammability hazard
Flammability (liquids)		Not applicable



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		explosion limit / Upper bility limit	:	No data available	
		explosion limit / Lower bility limit	:	No data available	
	Vapour	pressure	:	No data available	
	Relative	e vapour density	:	Not applicable	
	Relative	e density	:	No data available	
	Density	,	:	No data available	
	Solubili Wat	ty(ies) er solubility	:	No data available	
	Partitio octanol	n coefficient: n-	:	Not applicable	
		nition temperature	:	No data available	
	Decom	position temperature	:	No data available	
	Viscosi Visc	ty osity, kinematic	:	Not applicable	
	Explosi	ve properties	:	Not explosive	
		ng properties	:		mixture is not classified as oxidizing.
	Particle	SI∠e	:	No data available	

Section 10: Stability and reactivity

Reactivity Chemical stability Possibility of hazardous reac- tions	:	Not classified as a reactivity hazard. Stable under normal conditions. Vapours may form explosive mixture with air. Can react with strong oxidizing agents.
Conditions to avoid Incompatible materials Hazardous decomposition products	:	None known. Oxidizing agents No hazardous decomposition products are known.

Section 11: Toxicological information

Exposure routes	: Skin contact
	Ingestion
	Eye contact

Acute toxicity

Not classified based on available information.



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<u>Com</u>	oonents:			
Petro	latum:			
	oral toxicity	Method	Rat): > 5,000 mg/kg d: OECD Test Guideline 401 ks: Based on data from similar materials	
Acute	dermal toxicity	Methoo Assess toxicity	Rat): > 2,000 mg/kg d: OECD Test Guideline 402 sment: The substance or mixture has no acute de ks: Based on data from similar materials	erm
Paraf	fin oil:			
Acute	oral toxicity	: LD50 (I	Rat): > 5,000 mg/kg	
Acute	dermal toxicity		Rabbit): > 2,000 mg/kg sment: The substance or mixture has no acute d	erm
betan	nethasone:			
Acute	oral toxicity	: LD50 (I	Rat): > 5,000 mg/kg	
		LD50 (I	Mouse): > 4,500 mg/kg	
Acute	inhalation toxicity		Rat): 0.4 mg/l ure time: 4 h	
-	corrosion/irritation assified based on ava	ilable informat	ion.	
<u>Com</u>	oonents:			
Petro	latum:			
Speci Metho Resul Rema	od t	: No skir	Test Guideline 404 n irritation on data from similar materials	
Paraf	fin oil:			
Speci Resul		: Rabbit : No skir	ritation	
betan	nethasone:			
Speci Resul		: Rabbit : Mild sk	in irritation	

Not classified based on available information.



rsion	Revision Date: 09.04.2021	SDS Number: 1841076-00009	Date of last issue: 10.10.2020 Date of first issue: 19.07.2017
<u>Comp</u>	onents:		
Petrol	atum:		
Specie	es	: Rabbit	
Result		: No eye irritatio	n
Metho	d	: OECD Test Gu	uideline 405
Rema	rks	: Based on data	from similar materials
Paraff	in oil:		
Specie	es	: Rabbit	
Result		: No eye irritatio	n
betam	ethasone:		
Specie	es	: Rabbit	
Result		: No eye irritatio	n
Respi	ratory or skin sens	itisation	
Skin s	ensitisation		
Not cla	assified based on av	ailable information.	
Respi	ratory sensitisatior	1	
-	assified based on av		
<u>Comp</u>	onents:		
Petrol			
Test T		: Buehler Test	
	ure routes	: Skin contact	
Specie Result		: Guinea pig : negative	
Rema			from similar materials
hetam	ethasone:		
	ure routes	: Dermal	
Specie		: Guinea pig	
Result		: Weak sensitize	er
Chron	ic toxicity		
Germ	cell mutagenicity		
	assified based on av	ailable information.	
<u>Comp</u>	onents:		
Petrol			
Genot	oxicity in vitro	Result: negativ	
		Remarks: Base	ed on data from similar materials
Genot	oxicity in vivo	: Test Type: Ma cytogenetic as Species: Mous	



ersion 7	Revision Date: 09.04.2021			Date of last issue: 10.10.2020 Date of first issue: 19.07.2017
			Method: OECD Tes Result: negative	Intraperitoneal injection st Guideline 474 n data from similar materials
betan	nethasone:			
Geno	toxicity in vitro	:	Test Type: Bacteria Result: negative	al reverse mutation assay (AMES)
			Test Type: In vitro r Result: negative	mammalian cell gene mutation test
			Test Type: Chromo Result: positive	some aberration test in vitro
Geno	toxicity in vivo	:	Test Type: Mamma cytogenetic assay) Species: Mouse Application Route: Result: equivocal	ilian erythrocyte micronucleus test (in vivo Oral
	cell mutagenicity - ssment	:	Weight of evidence cell mutagen.	does not support classification as a germ
<u>Comp</u> Petro Speci Applic	cation Route sure time	: :	nformation. Rat Ingestion 2 Years negative	
-	oductive toxicity lamage the unborn chi	ld	-	
-	oonents:			
Petro	latum:			
	s on fertility	:	test Species: Rat Application Route: Result: negative	uction/Developmental toxicity screening Ingestion n data from similar materials
Effect ment	s on foetal develop-	:	Species: Rat Application Route: Result: negative	-foetal development Skin contact n data from similar materials



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betar	nethasone:				
Effect	ts on foetal develop-	:	Application Route Developmental T	e: Intramuscular oxicity: LOAEL: 0.05 mg/kg body weight ity, Malformations were observed.	
				e: Subcutaneous Toxicity: LOAEL: 0.42 mg/kg body weight ations were observed.	
				e: Intramuscular oxicity: LOAEL: 1 mg/kg body weight ations were observed.	
Repro sessr	oductive toxicity - As- nent	:	Clear evidence o animal experime	of adverse effects on development, based or nts.	
	Γ - single exposure lassified based on avail	lable	information.		
STO	Γ - repeated exposure				
Caus		Pituita		e system, muscle, thymus gland, Blood, Ad- re.	
<u>Com</u>	ponents:				
betar	nethasone:				
Targe	et Organs	:		mmune system, muscle, thymus gland, Bloo	
Asse	Assessment		Adrenal gland Causes damage to organs through prolonged or repeated exposure.		
Repe	ated dose toxicity				
<u>Com</u>	ponents:				
Petro	platum:				
Spec		:	Rat		
	EL cation Route sure time	:	5,000 mg/kg Ingestion 2 yr		
Paraf	ffin oil:				
Spec	ies	:	Rat, female		
	EL cation Route sure time	:	161 mg/kg Ingestion 90 Days		
betar	nethasone:				
Speci LOAE	ies	:	Rabbit 0.05 %		



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Expo	cation Route sure time et Organs	 Skin contact 10 - 30 d Pituitary gland, Immune system, muscle 	
Expo		: Rat : 0.05 % : Skin contact : 8 Weeks : thymus gland	
Expo		 Mouse 0.1 % Skin contact 8 Weeks thymus gland 	
Expo		 Dog 0.05 mg/kg Oral 28 d Blood, thymus gland, Adrenal gland 	
-	r ation toxicity lassified based on ava	able information.	
Com	ponents:		

Paraffin oil:

The substance or mixture is known to cause human aspiration toxicity hazards or has to be regarded as if it causes a human aspiration toxicity hazard.

Experience with human exposure

betamethasone:	
	Target Organs: Adrenal gland Symptoms: Redness, pruritis, Irritation

Section 12: Ecological information

Ecotoxicity	
Components:	
Petrolatum:	
Toxicity to fish	 LL50 (Pimephales promelas (fathead minnow)): > 100 mg/l Exposure time: 96 h Test substance: Water Accommodated Fraction Method: OECD Test Guideline 203 Remarks: Based on data from similar materials
Toxicity to daphnia and other aquatic invertebrates	: EC50 (Daphnia magna (Water flea)): > 10,000 mg/l Exposure time: 48 h



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				Vater Accommodated Fraction on data from similar materials
Toxicit plants	y to algae/aquatic	:	100 mg/l Exposure time: 72 Test substance: V Method: OECD Te	Vater Accommodated Fraction
	y to daphnia and other c invertebrates (Chron- ity)	:	Exposure time: 21 Test substance: V	nagna (Water flea)): 10 mg/l l d Vater Accommodated Fraction on data from similar materials
Paraff	in oil:			
Toxicit	y to fish	:	Exposure time: 96 Test substance: V	nus maximus (turbot)): > 100 mg/l 5 h Vater Accommodated Fraction on data from similar materials
	y to daphnia and other c invertebrates	:	Exposure time: 48 Test substance: V	
Toxicit plants	y to algae/aquatic	:	Exposure time: 72 Test substance: V	na costatum (marine diatom)): > 100 mg/l 2 h Vater Accommodated Fraction on data from similar materials
			Exposure time: 72 Test substance: V	ema costatum (marine diatom)): > 1 mg/l 2 h Vater Accommodated Fraction on data from similar materials
betam	ethasone:			
	y to daphnia and other c invertebrates	:	EC50 (Americamy Exposure time: 96	
Toxicit plants	y to algae/aquatic	:	mg/l Exposure time: 72 Method: OECD Te	
			mg/l Exposure time: 72 Method: OECD Te	
Toxicit icity)	y to fish (Chronic tox-	:	NOEC (Pimephale Exposure time: 32	es promelas (fathead minnow)): 0.052 mg/l 2 d



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			Method: OECD Te	est Guideline 210
			NOEC (Oryzias la Exposure time: 21 Method: OECD Te	
aq	xicity to daphnia and other uatic invertebrates (Chron- toxicity)	:	NOEC (Daphnia r Exposure time: 21 Method: OECD Te	
Ре	rsistence and degradabili	ty		
<u>Cc</u>	omponents:			
Ре	trolatum:			
Bio	odegradability	:		31 %
Bi	oaccumulative potential			
<u>Cc</u>	omponents:			
Ра	raffin oil:			
	rtition coefficient: n- tanol/water	:	log Pow: > 4 Remarks: Calcula	tion
be	tamethasone:			
	rtition coefficient: n- tanol/water	:	log Pow: 2.11	
	bbility in soil data available			
	her adverse effects data available			

Section 13: Disposal considerations

Disposal methods	
Waste from residues Contaminated packaging	Dispose of in accordance with local regulations. Empty containers should be taken to an approved waste han- dling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

Section 14: Transport information

International Regulations

UNRTDG

UN number	:	UN 3077



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Prope	er shipping name	: ENVIRONME N.O.S. (betamethasc	NTALLY HAZARDOUS SUBSTANCE, SOLID,	
Class Packi Label	ing group	: 9 : III : 9	, ,	
UN/IE	er shipping name	: UN 3077 : Environmenta (betamethaso : 9	lly hazardous substance, solid, n.o.s. one)	
Packi Label Packi aircra	ing group ls ing instruction (cargo	: III : Miscellaneous : 956 : 956		
ger ai	ircraft) onmentally hazardous	: yes		
UN n	G-Code umber er shipping name	: UN 3077 : ENVIRONME N.O.S. (betamethaso	NTALLY HAZARDOUS SUBSTANCE, SOLID,	
Label EmS	ing group	: 9 : III : 9 : F-A, S-F : yes		
	Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not applicable for product as supplied.			
Natio	National Regulations			
	5433 umber er shipping name	: UN 3077 : ENVIRONME N.O.S. (betamethaso	NTALLY HAZARDOUS SUBSTANCE, SOLID,	
Class Packi	ing group	: 9 : III	, ,	

Special precautions for user

: 9

: 2Z

Labels

Hazchem Code

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

Section 15: Regulatory information

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



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HSNO Approval Number

HSR100425 Pharmaceutical Active Ingredients Group Standard 2017

HSW Controls

Certified handler certificate not required. Tracking hazardous substance not required. Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.

The components of this product are reported in the following inventories:			
AICS	:	not determined	
DSL	:	not determined	
IECSC	:	not determined	

Section 16: Other information

Eurther information

Furt	iner information				
	rces of key data used to pile the Safety Data et	:	Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, http://echa.europa.eu/		
Date	e format	:	dd.mm.yyyy		
Full	Full text of other abbreviations				
ACO	ЯН	:	USA. ACGIH Threshold Limit Values (TLV)		
NZ (OEL	:	New Zealand. Workplace Exposure Standards for Atmospher-		
			ic Contaminants		
ACG	GIH / TWA	:	8-hour, time-weighted average		
NZ (OEL / WES-TWA	:	Workplace Exposure Standard - Time Weighted average		
NZ (OEL / WES-STEL	:	Workplace Exposure Standard - Short-Term Exposure Limit		

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



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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; 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.

NZ / EN