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Section 1: Identification

Product identifier :		Mometasone Metered Dose Inhaler Formulation	
Recommended use of the che	m	ical and restrictions on use	
	:	Pharmaceutical	
Restrictions on use	:	Not applicable	
Manufacturer or supplier's det	tai	ls	
Company	:	Organon & Co.	
Address	:	30 Hudson Street, 33nd floor Jersey City, New Jersey, U.S.A 07302	
Telephone	:	+1-551-430-6000	
Emergency telephone number	:	+1-215-631-6999	
E-mail address	:	EHSSTEWARD@organon.com	

: Category 3

Section 2: Hazard identification

Aerosols

Classification of the substance or mixture

Long-term (chronic) aquatic hazard	:	Category 2
GHS Label elements, includin	ng	precautionary statements
Hazard pictograms	:	¥2
Signal word	:	Warning
Hazard statements	:	H229 Pressurised container: May burst if heated. H411 Toxic to aquatic life with long lasting effects.
Precautionary statements	:	Prevention: P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P251 Do not pierce or burn, even after use. P273 Avoid release to the environment.



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Response: P391 Collect spillage.
Storage: P410 + P412 Protect from sunlight. Do not expose to tempera- tures exceeding 50 °C/ 122 °F.
Disposal: P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards which do not result in classification

May displace oxygen and cause rapid suffocation.

Section 3: Composition/information on ingredients

Substance / Mixture	:	Mixture
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Components

Chemical name	CAS-No.	Concentration (% w/w)
Ethanol#	64-17-5	>= 1.8 -<= 2.5
Mometasone	83919-23-7	>= 0.08 -<= 0.18

Voluntarily-disclosed substance

Section 4: First-aid measures

Description of necessary 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. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention immediately.			
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					
Risks	:	Gas reduces oxygen available for breathing.			



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Prote	ction of first-aiders	:	and use the reco	ders should pay attention to self-protection, ommended personal protective equipment al for exposure exists (see section 8).
Indic	ation of any immediate	me	dical attention a	nd special treatment needed
Treat	ment	:	Treat symptoma	tically and supportively.
Section 5	: Fire-fighting measure	s		
Exting	guishing media			
Suita	ble extinguishing media	:	Water spray Alcohol-resistant Carbon dioxide (Dry chemical	
Unsu media	itable extinguishing a	:	None known.	
Spec	ial hazards arising from	n th	e substance or r	nixture
Spec fightir	ific hazards during fire- ng	:		nbustion products may be a hazard to health re rises there is danger of the vessels burstir apor pressure.
Haza ucts	Hazardous combustion prod- ucts		Carbon oxides Fluorine compou	inds
Spec	ial protective actions for	or fi	re-fighters	
for fir	ial protective equipment efighters ific extinguishing meth-	:	Use personal pro Use extinguishin cumstances and Use water spray	re, wear self-contained breathing apparatus. otective equipment. g measures that are appropriate to local cir- the surrounding environment. to cool unopened containers. aged containers from fire area if it is safe to o

Section 6: Accidental release measures

Personal precautions, protective e	equipment and emergency procedures
Personal precautions :	Evacuate personnel to safe areas. Ventilate the area. Use personal protective equipment. Follow safe handling advice (see section 7) and personal pro- tective equipment recommendations (see section 8).
Environmental precautions Environmental precautions :	Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Prevent spreading over a wide area (e.g. by containment or oil barriers). Retain and dispose of contaminated wash water.



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Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for containment and cleaning up

Methods for cleaning up	F r t t t t r f f f f f f f f f f t t t t	Soak up with inert absorbent material. For large spills, provide dyking or other appropriate contain- ment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absor- bent. Local or national regulations may apply to releases and dis- bosal of this material, as well as those materials and items employed in the cleanup of releases. You will need to deter- nine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.
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Section 7: Handling and storage

Precautions for safe handling	
Technical measures :	See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
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 vapours or spray mist. 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. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Take care to prevent spills, waste and minimize release to the
Hygiene measures :	environment. 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 contaminated clothing before re-use.
Conditions for safe storage, in	cluding any incompatibilities
Conditions for safe storage :	Keep tightly closed. Keep in a cool, well-ventilated place. Store in accordance with the particular national regulations. Do not pierce or burn, even after use. Keep cool. Protect from sunlight.
Materials to avoid :	Do not store with the following product types: Strong oxidizing agents



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Section 8: Exposure controls/personal protection

Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis
Ethanol	64-17-5	PEL (long term)	1,000 ppm 1,880 mg/m3	SG OEL
		STEL	1,000 ppm	ACGIH
Mometasone	83919-23-7	TWA	1 µg/m3 (OEB 4)	Internal
	Further information: Skin			
		Wipe limit	10 µg/100 cm ²	Internal

Individual protection measures, such as personal protective equipment (PPE)

Skin protection Respiratory protection		Skin should be washed after contact. If adequate local exhaust ventilation is not available or expo- sure assessment demonstrates exposures outside the rec- ommended guidelines, use respiratory protection.
Filter type	:	Self-contained breathing apparatus

Section 9: Physical and chemical properties

Appearance	:	Aerosol containing a dissolved gas
Colour	:	white to off-white
Odour	:	odourless
Odour Threshold	:	No data available
рН	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	-16 °C
Flash point	:	No data available
Evaporation rate	:	No data available
Flammability (solid, gas)	:	Not applicable
Flammability (liquids)	:	No data available



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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	9
	Relativ	e vapour density	:	No data available	9
	Relativ	e density	:	No data available	9
l	Density	,	:	1 g/cm ³	
11	Solubili Wat	ty(ies) er solubility	:	insoluble	
	Partitio octanol	n coefficient: n-	:	No data available)
		nition temperature	:	No data available)
	Decom	position temperature	:	No data available)
	Viscosi Visc	ty cosity, kinematic	:	No data available)
	Explosi	ve properties	:	Not explosive	
	Oxidiziı	ng properties	:	The substance of	r mixture is not classified as oxidizing.
	Molecu	lar weight	:	No data available	9
11	Particle Particle	e characteristics e size	:	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. If the temperature rises there is danger of the vessels bursting due to the high vapor pressure. Can react with strong oxidizing agents.
Conditions to avoid Incompatible materials Hazardous decomposition products		None known. Oxidizing agents No hazardous decomposition products are known.



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Information on likely routes of exposure	:	Inhalation Skin contact Ingestion Eye contact
Acute toxicity		
Not classified based on availab	ole	information.
Components:		
Ethanol:		
Acute oral toxicity	:	LD50 (Rat): > 5,000 mg/kg Method: OECD Test Guideline 401
Acute inhalation toxicity	:	LC50 (Rat): 124.7 mg/l Exposure time: 4 h Test atmosphere: vapour
Mometasone:		
Acute oral toxicity	:	LD50 (Rat): > 2,000 mg/kg
		LD50 (Mouse): > 2,000 mg/kg
Acute inhalation toxicity	:	LC50 (Rat): > 3.3 mg/l Exposure time: 4 h Test atmosphere: dust/mist Remarks: No mortality observed at this dose.
		LC50 (Mouse): > 3.2 mg/l Exposure time: 4 h Test atmosphere: dust/mist
Acute toxicity (other routes of administration)	:	LD50 (Rat): 300 mg/kg Application Route: Subcutaneous Symptoms: Breathing difficulties
Skin corrosion/irritation Not classified based on availab	ole	information.
Components:		
Ethanol:		
Species Method	:	Rabbit OECD Test Guideline 404

Mometasone:



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Species Result

: Rabbit : No skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Ethanol:

Species :	Rabbit
Species : Result : Method :	Irritation to eyes, reversing within 21 days
Method :	OECD Test Guideline 405

Mometasone:

Species Result	:	Rabbit
Result	:	No eye irritation

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:

Ethanol:

Test Type	:	Local lymph node assay (LLNA)
Exposure routes	:	Skin contact
Species Result	:	Mouse
Result	:	negative

Mometasone:

Test Type	: Maximisation Test
Exposure routes	: Dermal
Species	: Guinea pig
Assessment	: Does not cause skin sensitisation.
Result	: negative
Test Type Exposure routes Species Assessment Result Remarks	: The results of a test on guinea pigs showed this substance to be a weak skin sensitiser.

Germ cell mutagenicity

Not classified based on available information.

Components:

Ethanol:

Genotoxicity in vitro

: Test Type: In vitro mammalian cell gene mutation test



ersion 0	Revision Date: 06.04.2024	SDS Number: 26004-00024	Date of last issue: 26.09.2023 Date of first issue: 28.10.2014
		Result: nega Test Type: B Result: nega	acterial reverse mutation assay (AMES)
Geno	toxicity in vivo	Species: Mo	Route: Ingestion
Mome	etasone:		
Geno	toxicity in vitro	: Test Type: B Result: nega	acterial reverse mutation assay (AMES) tive
			hromosomal aberration Chinese hamster lung cells tive
			hromosomal aberration Chinese hamster ovary cells ive
		Test Type: M Result: nega	louse Lymphoma tive
Geno	toxicity in vivo	: Test Type: M Species: Mo Application F Result: nega	Route: Oral
		Test Type: C Species: Rat Cell type: Bo Result: nega	ne marrow
		Test Type: u Species: Rat Cell type: Liv Result: nega	ver cells
	cell mutagenicity - ssment	: Weight of ev cell mutagen	idence does not support classification as a germ
	nogenicity assified based on ava	ailable information.	
	oonents:		
	etasone:		
Speci	es	: Rat	



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Expos Dose Resul Speci Applic	es cation Route sure time	 Inhalation 2 Years 0.067 mg/kg negative Mouse Inhalation 19 Months 0.160 mg/kg negative 	
-	oductive toxicity assified based on avai	lable information.	
	ponents:		
Ethar			
Effect	s on fertility	Species: Mou	oute: Ingestion
Mome	etasone:		
Effect	s on fertility	Fertility: NOA Symptoms: R weight	ertility oute: Subcutaneous EL: 0.015 mg/kg body weight Reduced embryonic survival, Reduced foetal fects on fertility, Effect on reproduction capacity
Effect ment	s on foetal develop-	Species: Mou Application R Embryo-foeta	mbryo-foetal development use oute: Subcutaneous al toxicity: LOAEL: 0.06 mg/kg body weight yotoxic effects., Teratogenicity and developmen
		Species: Rat Application R Embryo-foeta	mbryo-foetal development oute: Dermal al toxicity: LOAEL: 0.3 mg/kg body weight yo-foetal toxicity
		Species: Rab Application R Embryo-foeta	



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		Species: Rat Application F Embryo-foet	mbryo-foetal development t Route: Subcutaneous al toxicity: LOAEL: 0.15 mg/kg body weight cts on newborn
		Species: Ral Application F Embryo-foet	
Repro sessr	oductive toxicity - As- nent	animal expe	nce of adverse effects on development, based on riments., Some evidence of adverse effects on ion and fertility, based on animal experiments.
	- single exposure		
	lassified based on avai ponents:	able information.	
-	etasone:		
Rema	arks	: Based on av	railable data, the classification criteria are not me
STOT	- repeated exposure		
	lassified based on avai	able information.	
	ponents:		
Expos Targe	etasone: sure routes et Organs ssment	: Immune syst	ust/mist/fume) tem, Liver, Kidney, Skin lamage to organs through prolonged or repeated
Repe	ated dose toxicity		
Com	ponents:		
Ethar	nol:		
	ΞL	: Rat : 1,280 mg/kg : 3,156 mg/kg : Ingestion : 90 Days	
Mom	etasone:		
Speci NOAI	ies	: Rat : 0.005 mg/kg	



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Expo Targe Spec LOAE Appli Expo	cation Route sure time et Organs ies	: Dog : 0.5 mg/kg : Oral : 30 d	es, Liver, Adrenal gland, Skin, thymus gland es, Liver, Adrenal gland, Skin, thymus gland
Expo		: 90 d : Adrenal glai	/l lust/mist/fume) nd, Lungs, Lymph nodes, spleen, Bone marrow, er, thymus gland
Expo		: 90 d : Adrenal glai	lust/mist/fume) nd, Lungs, Lymph nodes, spleen, Bone marrow, nus gland, Liver
Not c <u>Com</u> Mom	ration toxicity lassified based on ava ponents: etasone: pplicable	ailable information.	
Expe	rience with human e	xposure	
Mom Inhala Skin	ponents: etasone: ation contact ner information	piratory trac musculoske	allergic rhinitis, Headache, pharyngitis, upper res- t infection, sinusitis, oral candidiasis, Back pain, letal pain, immune system effects, indigestion Dermatitis, Itching
	ponents: etasone: arks	: Dermal abs	orption possible



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Section 12: Ecological information

Toxicity		
Components:		
Ethanol:		
Toxicity to fish	:	LC50 (Pimephales promelas (fathead minnow)): > 1,000 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Ceriodaphnia (water flea)): > 1,000 mg/l Exposure time: 48 h
Toxicity to algae/aquatic plants	:	ErC50 (Chlorella vulgaris (Fresh water algae)): 275 mg/l Exposure time: 72 h
		EC10 (Chlorella vulgaris (Fresh water algae)): 11.5 mg/l Exposure time: 72 h
Toxicity to daphnia and other aquatic invertebrates (Chron- ic toxicity)	:	NOEC (Daphnia magna (Water flea)): 9.6 mg/l Exposure time: 9 d
Toxicity to microorganisms	:	EC50 (Pseudomonas putida): 6,500 mg/l Exposure time: 16 h
Mometasone:		
Toxicity to fish	:	LC50 (Menidia beryllina (Silverside)): 0.11 mg/l Exposure time: 96 h Remarks: No toxicity at the limit of solubility
		LC50 (Cyprinodon variegatus (sheepshead minnow)): > 5 mg/l Exposure time: 7 d Remarks: No toxicity at the limit of solubility
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): > 5 mg/l Exposure time: 48 h Method: OECD Test Guideline 202 Remarks: No toxicity at the limit of solubility
		EC50 (Americamysis): > 5 mg/l Exposure time: 96 h Method: US-EPA OPPTS 850.1035 Remarks: No toxicity at the limit of solubility
Toxicity to algae/aquatic plants	:	EC50 (Pseudokirchneriella subcapitata (green algae)): > 3.2 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 Remarks: No toxicity at the limit of solubility



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Toxici icity)	ity to fish (Chronic tox-	:	NOEC (Pimephale mg/l Exposure time: 32 Method: OECD Te	
	ity to daphnia and other ic invertebrates (Chron- icity)	:	Exposure time: 21 Method: OECD Te	
	ctor (Chronic aquatic	:	100	
toxicit Toxici	y) ity to microorganisms	:	EC50: > 1,000 mg Exposure time: 3 Test Type: Respir Method: OECD Te Remarks: No toxid	h ation inhibition
			NOEC: 1,000 mg/ Exposure time: 3 Test Type: Respir Method: OECD Te Remarks: No toxid	h ation inhibition
	stence and degradabili	ity		
	<u>oonents:</u>			
Ethar Biode	i oi: gradability	:	Result: Readily bio Biodegradation: 8 Exposure time: 20	34 %
Mome	etasone:			
Biode	gradability	:	Result: Not readily Biodegradation: 5 Exposure time: 28 Method: OECD Te	50 % 3 d
Stabil	ity in water	:	Hydrolysis: 50 %(Method: OECD Te	
Bioad	cumulative potential			
Com	oonents:			
	nol: ion coefficient: n- ol/water	:	log Pow: -0.35	



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Mom	etasone:			
Bioac	cumulation	:	Bioconcentratio	nis macrochirus (Bluegill sunfish) on factor (BCF): 107.1 9 Test Guideline 305
	ion coefficient: n- ol/water	:	log Pow: 4.68	
Mobi	lity in soil			
<u>Com</u>	oonents:			
Distril	etasone: oution among environ- al compartments	:	log Koc: 4.02	
	r adverse effects ata available			

Section 13: Disposal considerations

Waste from residues	:	Do not dispose of waste into sewer. Dispose of in accordance with local regulations.
Contaminated packaging	:	Please ensure aerosol cans are sprayed completely empty (including propellant) 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 1950
UN proper shipping name	:	AEROSOLS
Transport hazard class(es)	:	2.2
Packing group	:	Not assigned by regulation
Labels	:	2.2
Environmental hazards	:	no
IATA-DGR		
UN/ID No.	:	UN 1950
UN proper shipping name	:	Aerosols, non-flammable
Transport hazard class(es)	:	2.2
Packing group	:	Not assigned by regulation
Labels	:	Non-flammable, non-toxic Gas
Packing instruction (cargo	:	203
aircraft)		
Packing instruction (passen-	:	203



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ger aircraft)

IMDG-Code		
UN number	:	UN 1950
Proper shipping name	:	AEROSOLS
		(Mometasone)
Transport hazard class(es)	:	2.2
Packing group	:	Not assigned by regulation
Labels	:	2.2
EmS Code	:	F-D, S-U
Marine pollutant	:	yes

Transport in bulk according to IMO instruments

Not applicable for product as supplied.

Special precautions for user

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 specific for the product in question

Workplace Safety and Health Act and Workplace Safety and Health (General Provisions) Regulations: This product is subjected to the SDS, labelling, PEL and other requirements in the Act/Regulations.

	n and Management Act and n and Management (Hazard- ations	:	Hydrofluorocarbons
Fire Safety (Petroleum a Regulations	and Flammable Materials)	:	Not applicable
Montreal Protocol		:	1,1,1,2,3,3,3-Heptafluoropropane
The components of th AICS	is product are reported in the : not determined	foll	owing inventories:
DSL	: not determined		
IECSC	: not determined		
Section 16: Other informat	ion		

Revision Date : 06.04.2024 Further information : Internal technical data, data from raw material SDSs, OECD



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compile the Safety Data Sheet eChem Portal search results and European Chemicals Agency, http://echa.europa.eu/

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Date format

: dd.mm.yyyy

SG OEL / PEL (long term) : Permissible Exposure Level (PEL) Long Term

Full text of other abbreviations				
ACGIH SG OEL	:	USA. ACGIH Threshold Limit Values (TLV) Singapore. Workplace Safety and Health (General Provisions) Regulations - First Schedule Permissible Exposure Limits of Toxic Substances.		
ACGIH / STEL	:	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 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



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considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

SG / EN