

Mometasone Metered Dose Inhaler Formulation

Version 3.13 Revision Date: 09.04.2021 SDS Number: 26001-00017 Date of last issue: 16.10.2020
Date of first issue: 28.10.2014

Section 1: Identification

Product name : Mometasone Metered Dose Inhaler Formulation

Manufacturer or supplier's details

Company : Organon & Co.

Address : 30 Hudson Street, 33rd floor
Jersey City, New Jersey, U.S.A 07302

Telephone : 551-430-6000

Emergency telephone number : 215-631-6999

E-mail address : EHSSTEWARD@organon.com

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

Section 2: Hazard identification

GHS Classification

Gases under pressure : Dissolved gas

GHS label elements

Hazard pictograms :



Signal word : Warning

Hazard statements : H280 Contains gas under pressure; may explode if heated.

Precautionary statements : **Storage:**
P410 + P403 Protect from sunlight. Store in a well-ventilated place.

Other hazards which do not result in classification

May displace oxygen and cause rapid suffocation.

Section 3: Composition/information on ingredients

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Ethanol#	64-17-5	>= 1.8 -<= 2.5

SAFETY DATA SHEET



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Mometasone	83919-23-7	>= 0.08 -<= 0.18
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Voluntarily-disclosed non-hazardous substance

Section 4: First-aid measures

- General advice : In the case of accident or if you feel unwell, seek medical advice 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 : Gas reduces oxygen available for breathing.
- 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 : Water spray
Alcohol-resistant foam
Carbon dioxide (CO₂)
Dry chemical
- Unsuitable extinguishing media : None known.
- Specific hazards during fire-fighting : Exposure to combustion products may be a hazard to health.
If the temperature rises there is danger of the vessels bursting due to the high vapor pressure.
- Hazardous combustion products : Carbon oxides
Fluorine compounds
- Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Use water spray to cool unopened containers.
Remove undamaged containers from fire area if it is safe to do so.

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Special protective equipment for firefighters	:	Evacuate area. In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.
Hazchem Code	:	2YE

Section 6: Accidental release measures

Personal precautions, protective equipment and emergency procedures	:	Evacuate personnel to safe areas. Ventilate the area. Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
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. Local authorities should be advised if significant spillages cannot be contained.
Methods and materials for containment and cleaning up	:	Soak up with inert absorbent material. For large spills, provide dyking or other appropriate containment 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 absorbent. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

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.
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 assessment 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 environment.
Hygiene measures	:	If exposure to chemical is likely during typical use, provide eye

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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 : 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

Section 8: Exposure controls/personal protection

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Ethanol	64-17-5	WES-TWA	1,000 ppm 1,880 mg/m ³	NZ OEL
		STEL	1,000 ppm	ACGIH
Mometasone	83919-23-7	TWA	1 µg/m ³ (OEB 4)	Internal
	Further information: Skin			
		Wipe limit	10 µg/100 cm ²	Internal

Personal protective equipment

Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type : Self-contained breathing apparatus

Skin and body protection : Skin should be washed after contact.

Section 9: Physical and chemical properties

Appearance : Aerosol containing a dissolved gas

Colour : white to off-white

Odour : odourless

Odour Threshold : No data available

pH : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling range : -16 °C

Flash point : No data available

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Evaporation rate	:	No data available
Flammability (solid, gas)	:	Not applicable
Flammability (liquids)	:	No data available
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
Density	:	1 g/cm ³
Solubility(ies)		
Water solubility	:	insoluble
Partition coefficient: n-octanol/water	:	No data available
Auto-ignition temperature	:	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.
Molecular weight	:	No data available
Particle size	:	No data available

Section 10: Stability and reactivity

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	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	:	None known.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.

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Section 11: Toxicological information

Exposure routes : Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity

Not classified based on available 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 available information.

Components:**Ethanol:**

Species : Rabbit
Method : OECD Test Guideline 404
Result : No skin irritation

Mometasone:

Species : Rabbit
Result : No skin irritation

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Serious eye damage/eye irritation

Not classified based on available information.

Components:**Ethanol:**

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

Mometasone:

Species : 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 : Mouse
Result : negative

Mometasone:

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

Chronic toxicity**Germ cell mutagenicity**

Not classified based on available information.

Components:**Ethanol:**

Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test
Result: negative

Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

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Genotoxicity in vivo : Test Type: Rodent dominant lethal test (germ cell) (in vivo)
Species: Mouse
Application Route: Ingestion
Result: equivocal

Mometasone:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Test Type: Chromosomal aberration
Test system: Chinese hamster lung cells
Result: negative

Test Type: Chromosomal aberration
Test system: Chinese hamster ovary cells
Result: positive

Test Type: Mouse Lymphoma
Result: negative

Genotoxicity in vivo : Test Type: Micronucleus test
Species: Mouse
Application Route: Oral
Result: negative

Test Type: Chromosomal aberration
Species: Rat
Cell type: Bone marrow
Result: negative

Test Type: unscheduled DNA synthesis assay
Species: Rat
Cell type: Liver cells
Result: negative

Germ cell mutagenicity - Assessment : Weight of evidence does not support classification as a germ cell mutagen.

Carcinogenicity

Not classified based on available information.

Components:

Mometasone:

Species : Rat
Application Route : Inhalation
Exposure time : 2 Years
Dose : 0.067 mg/kg body weight
Result : negative

Species : Mouse
Application Route : Inhalation

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Exposure time : 19 Months
 Dose : 0.160 mg/kg body weight
 Result : negative

Reproductive toxicity

Not classified based on available information.

Components:

Ethanol:

Effects on fertility : Test Type: Two-generation reproduction toxicity study
 Species: Mouse
 Application Route: Ingestion
 Result: negative

Mometasone:

Effects on fertility : Test Type: Fertility
 Species: Rat
 Application Route: Subcutaneous
 Fertility: NOAEL: 0.015 mg/kg body weight
 Symptoms: Reduced embryonic survival, Reduced foetal weight
 Result: No effects on fertility, Effect on reproduction capacity

Effects on foetal development : Test Type: Embryo-foetal development
 Species: Mouse
 Application Route: Subcutaneous
 Embryo-foetal toxicity: LOAEL: 0.06 mg/kg body weight
 Result: Embryotoxic effects., Teratogenicity and developmental toxicity

Test Type: Embryo-foetal development
 Species: Rat
 Application Route: Dermal
 Embryo-foetal toxicity: LOAEL: 0.3 mg/kg body weight
 Result: Embryo-foetal toxicity

Test Type: Embryo-foetal development
 Species: Rabbit
 Application Route: Dermal
 Embryo-foetal toxicity: LOAEL: 0.15 mg/kg body weight
 Result: Embryo-foetal toxicity, Malformations were observed.

Test Type: Embryo-foetal development
 Species: Rat
 Application Route: Subcutaneous
 Embryo-foetal toxicity: LOAEL: 0.15 mg/kg body weight
 Result: Effects on newborn

Test Type: Embryo-foetal development
 Species: Rabbit
 Application Route: Oral
 Embryo-foetal toxicity: LOAEL: 0.7 mg/kg body weight

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Result: Embryo-foetal toxicity, Malformations were observed.

Reproductive toxicity - Assessment : Clear evidence of adverse effects on development, based on animal experiments., Some evidence of adverse effects on sexual function and fertility, based on animal experiments.

STOT - single exposure

Not classified based on available information.

Components:

Mometasone:

Remarks : Based on available data, the classification criteria are not met.

STOT - repeated exposure

Not classified based on available information.

Components:

Mometasone:

Exposure routes : inhalation (dust/mist/fume)
 Target Organs : Immune system, Liver, Kidney, Skin
 Assessment : May cause damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

Ethanol:

Species : Rat
 NOAEL : 1,280 mg/kg
 LOAEL : 3,156 mg/kg
 Application Route : Ingestion
 Exposure time : 90 Days

Mometasone:

Species : Rat
 NOAEL : 0.005 mg/kg
 LOAEL : 0.3 mg/kg
 Application Route : Oral
 Exposure time : 30 d
 Target Organs : Lymph nodes, Liver, Adrenal gland, Skin, thymus gland

Species : Dog
 LOAEL : 0.5 mg/kg
 Application Route : Oral
 Exposure time : 30 d
 Target Organs : Lymph nodes, Liver, Adrenal gland, Skin, thymus gland

Species : Rat
 NOAEL : 0.00013 mg/l

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Application Route : inhalation (dust/mist/fume)
 Exposure time : 90 d
 Target Organs : Adrenal gland, Lungs, Lymph nodes, spleen, Bone marrow, Kidney, Liver, thymus gland

Species : Dog
 NOAEL : 0.0005 mg/l
 Application Route : inhalation (dust/mist/fume)
 Exposure time : 90 d
 Target Organs : Adrenal gland, Lungs, Lymph nodes, spleen, Bone marrow, Kidney, thymus gland, Liver

Aspiration toxicity

Not classified based on available information.

Components:

Mometasone:

Not applicable

Experience with human exposure

Components:

Mometasone:

Inhalation : Symptoms: allergic rhinitis, Headache, pharyngitis, upper respiratory tract infection, sinusitis, oral candidiasis, Back pain, musculoskeletal pain, immune system effects, indigestion
 Skin contact : Symptoms: Dermatitis, Itching

Further information

Components:

Mometasone:

Remarks : Dermal absorption possible

Section 12: Ecological information

Ecotoxicity

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

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EC10 (Chlorella vulgaris (Fresh water algae)): 11.5 mg/l
Exposure time: 72 h

Toxicity to daphnia and other aquatic invertebrates (Chronic 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

Toxicity to fish (Chronic toxicity) : NOEC (Pimephales promelas (fathead minnow)): 0.00014 mg/l
Exposure time: 32 d
Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 0.34 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 211
Remarks: No toxicity at the limit of solubility

Toxicity to microorganisms : EC50: > 1,000 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209
Remarks: No toxicity at the limit of solubility

NOEC: 1,000 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition

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Method: OECD Test Guideline 209
Remarks: No toxicity at the limit of solubility

Persistence and degradability**Components:****Ethanol:**

Biodegradability : Result: Readily biodegradable.
Biodegradation: 84 %
Exposure time: 20 d

Mometasone:

Biodegradability : Result: Not readily biodegradable.
Biodegradation: 50 %
Exposure time: 28 d
Method: OECD Test Guideline 314

Stability in water : Hydrolysis: 50 %(12 d)
Method: OECD Test Guideline 111

Bioaccumulative potential**Components:****Ethanol:**

Partition coefficient: n-octanol/water : log Pow: -0.35

Mometasone:

Bioaccumulation : Species: Lepomis macrochirus (Bluegill sunfish)
Bioconcentration factor (BCF): 107.1
Method: OECD Test Guideline 305

Partition coefficient: n-octanol/water : log Pow: 4.68

Mobility in soil**Components:****Mometasone:**

Distribution among environmental compartments : log Koc: 4.02

Other adverse effects

No data available

Section 13: Disposal considerations**Disposal methods**

Waste from residues : Dispose of in accordance with local regulations.
Contaminated packaging : Empty containers should be taken to an approved waste han-

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ding site for recycling or disposal.
If not otherwise specified: Dispose of as unused product.
Please ensure aerosol cans are sprayed completely empty
(including propellant)

Section 14: Transport information

International Regulations

UNRTDG

UN number	:	UN 1950
Proper shipping name	:	AEROSOLS
Class	:	2.2
Packing group	:	Not assigned by regulation
Labels	:	2.2

IATA-DGR

UN/ID No.	:	UN 1950
Proper shipping name	:	Aerosols, non-flammable
Class	:	2.2
Packing group	:	Not assigned by regulation
Labels	:	Non-flammable, non-toxic Gas
Packing instruction (cargo aircraft)	:	203
Packing instruction (passenger aircraft)	:	203

IMDG-Code

UN number	:	UN 1950
Proper shipping name	:	AEROSOLS (Mometasone)
Class	:	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 Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

National Regulations

NZS 5433

UN number	:	UN 1950
Proper shipping name	:	AEROSOLS
Class	:	2.2
Packing group	:	Not assigned by regulation
Labels	:	2.2
Hazchem Code	:	2YE

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.

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Section 15: Regulatory information**Safety, health and environmental regulations/legislation specific for the substance or mixture****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.

Montreal Protocol : 1,1,1,2,3,3,3-Heptafluoropropane

The components of this product are reported in the following inventories:

AICS : not determined

DSL : not determined

IECSC : not determined

Section 16: Other information**Further information**Sources of key data used to compile the Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Date format : dd.mm.yyyy

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

NZ OEL : New Zealand. Workplace Exposure Standards for Atmospheric Contaminants

ACGIH / STEL : Short-term exposure limit

NZ OEL / WES-TWA : Workplace Exposure Standard - Time Weighted 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 con-

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centration; 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; 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