

# SAFETY DATA SHEET



## Mometasone Dry Powder Inhaler Formulation



Version 5.1      Revision Date: 30.09.2023      SDS Number: 437330-00018      Date of last issue: 04.04.2023  
Date of first issue: 28.01.2016

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### SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Mometasone Dry Powder Inhaler Formulation

#### Manufacturer or supplier's details

Company name of supplier : Organon & Co.  
Address : Avenida 16 de Septiembre No. 301  
Xaltocan - Xochimilco Mexico 16090  
Telephone : +52 55 57284444  
Emergency telephone : 1-215-631-6999  
E-mail address : EHSSTEWARD@organon.com

#### Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical  
Restrictions on use : Not applicable


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### SECTION 2. HAZARDS IDENTIFICATION

#### GHS Classification

Reproductive toxicity : Category 1B  
Specific target organ toxicity : Category 2 (Immune system, Liver, Kidney, Skin)  
- repeated exposure  
(Inhalation)

#### GHS label elements

Hazard pictograms : 

Signal Word : Danger

Hazard Statements : H360Df May damage the unborn child. Suspected of damaging fertility.  
H373 May cause damage to organs (Immune system, Liver, Kidney, Skin) through prolonged or repeated exposure if inhaled.

Precautionary Statements : **Prevention:**  
P201 Obtain special instructions before use.  
P202 Do not handle until all safety precautions have been read and understood.  
P260 Do not breathe dust.  
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

**Response:**  
P308 + P313 IF exposed or concerned: Get medical advice/ attention.

**Storage:**

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P405 Store locked up.

### Disposal:

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

### Other hazards

Dust contact with the eyes can lead to mechanical irritation.  
Contact with dust can cause mechanical irritation or drying of the skin.  
May form explosive dust-air mixture during processing, handling or other means.

## SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

### Components

Chemical name	CAS-No.	Concentration (% w/w)
Mometasone	83919-23-7	>= 10 -< 20

## 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.  
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 the unborn child. Suspected of damaging fertility.  
May cause damage to organs through prolonged or repeated exposure if inhaled.  
Contact with dust can cause mechanical irritation or drying of the skin.  
Dust contact with the eyes can lead to mechanical irritation.

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

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		Alcohol-resistant foam Carbon dioxide (CO <sub>2</sub> ) Dry chemical
Unsuitable extinguishing media	:	None known.
Specific hazards during fire fighting	:	Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard. Exposure to combustion products may be a hazard to health.
Hazardous combustion products	:	Carbon oxides Chlorine 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. Evacuate area.
Special protective equipment for fire-fighters	:	In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

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### SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	:	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. 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	:	Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. 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.

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### SECTION 7. HANDLING AND STORAGE

Technical measures	:	Static electricity may accumulate and ignite suspended dust causing an explosion. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.
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- Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust ventilation.
- Advice on safe handling : Do not get on skin or clothing.  
Do not breathe dust.  
Do not swallow.  
Avoid contact with eyes.  
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment  
Keep container tightly closed.  
Minimize dust generation and accumulation.  
Keep container closed when not in use.  
Keep away from heat and sources of ignition.  
Take precautionary measures against static discharges.  
Take care to prevent spills, waste and minimize release to the environment.
- Hygiene measures : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.  
When using do not eat, drink or smoke.  
Wash contaminated clothing before re-use.  
The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.
- Conditions for safe storage : Keep in properly labeled containers.  
Store locked up.  
Keep tightly closed.  
Store in accordance with the particular national regulations.
- Materials to avoid : Do not store with the following product types:  
Strong oxidizing agents  
Self-reactive substances and mixtures  
Organic peroxides  
Explosives  
Gases

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Mometasone	83919-23-7	TWA	1 µg/m <sup>3</sup> (OEB 4)	Internal
Further information: Skin				
		Wipe limit	10 µg/100 cm <sup>2</sup>	Internal

- 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 stationary container, ventilated enclosure, etc.).

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All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. Essentially no open handling permitted. Use closed processing systems or containment technologies.

**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	:	Particulates type
Hand protection	:	
Material	:	Chemical-resistant gloves
Remarks	:	Consider double gloving.
Eye protection	:	Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.
Skin and body protection	:	Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.

**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance	:	powder
Color	:	white
Odor	:	No data available
Odor Threshold	:	No data available
pH	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	Not applicable
Evaporation rate	:	No data available
Flammability (solid, gas)	:	May form explosive dust-air mixture during processing, handling or other means.
Flammability (liquids)	:	No data available

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Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

Vapor pressure : No data available

Relative vapor density : No data available

Relative density : No data available

Density : No data available

Solubility(ies)  
Water solubility : No data available

Partition coefficient: n-octanol/water : No data available

Autoignition 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

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### SECTION 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.

Chemical stability : Stable under normal conditions.

Possibility of hazardous reactions : May form explosive dust-air mixture during processing, handling or other means.  
Can react with strong oxidizing agents.

Conditions to avoid : Heat, flames and sparks.  
Avoid dust formation.

Incompatible materials : Oxidizing agents

Hazardous decomposition products : No hazardous decomposition products are known.

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### SECTION 11. TOXICOLOGICAL INFORMATION

#### Information on likely routes of exposure

Inhalation  
Skin contact  
Ingestion  
Eye contact

#### Acute toxicity

Not classified based on available information.

#### Components:

##### 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:

##### Mometasone:

Species : Rabbit  
Result : No skin irritation

#### Serious eye damage/eye irritation

Not classified based on available information.

#### Components:

##### Mometasone:

Species : Rabbit  
Result : No eye irritation

#### Respiratory or skin sensitization

##### Skin sensitization

Not classified based on available information.

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**Respiratory sensitization**

Not classified based on available information.

**Components:****Mometasone:**

Test Type	:	Maximization Test
Routes of exposure	:	Dermal
Species	:	Guinea pig
Assessment	:	Does not cause skin sensitization.
Result	:	negative
Remarks	:	The results of a test on guinea pigs showed this substance to be a weak skin sensitizer.

**Germ cell mutagenicity**

Not classified based on available information.

**Components:****Mometasone:**

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

Not classified based on available information.



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

### **Reproductive toxicity**

May damage the unborn child. Suspected of damaging fertility.

### Components:

#### **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 fetal weight.  
Result: No effects on fertility., Effect on reproduction capacity.

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

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

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

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

Test Type: Embryo-fetal development

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Species: Rabbit  
 Application Route: Oral  
 Embryo-fetal toxicity.: LOAEL: 0.7 mg/kg body weight  
 Result: Embryo-fetal 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**

May cause damage to organs (Immune system, Liver, Kidney, Skin) through prolonged or repeated exposure if inhaled.

**Components:****Mometasone:**

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

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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
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**SECTION 12. ECOLOGICAL INFORMATION****Ecotoxicity****Components:****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

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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

Method: OECD Test Guideline 209

Remarks: No toxicity at the limit of solubility.

**Persistence and degradability****Components:****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:****Mometasone:**

Bioaccumulation : Species: Lepomis macrochirus (Bluegill sunfish)

Bioconcentration factor (BCF): 107.1

Method: OECD Test Guideline 305

Partition coefficient: n- : log Pow: 4.68

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octanol/water

### Mobility in soil

### Components:

#### Mometasone:

Distribution among environmental compartments : log Koc: 4.02

#### Other adverse effects

No data available

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## SECTION 13. DISPOSAL CONSIDERATIONS

### Disposal methods

Waste from residues : Do not dispose of waste into sewer.  
Dispose of in accordance with local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.  
If not otherwise specified: Dispose of as unused product.

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## SECTION 14. TRANSPORT INFORMATION

### International Regulations

#### UNRTDG

UN number : UN 3077  
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.  
(Mometasone)

Class : 9  
Packing group : III  
Labels : 9  
Environmentally hazardous : yes

#### IATA-DGR

UN/ID No. : UN 3077  
Proper shipping name : Environmentally hazardous substance, solid, n.o.s.  
(Mometasone)

Class : 9  
Packing group : III  
Labels : Miscellaneous  
Packing instruction (cargo aircraft) : 956  
Packing instruction (passenger aircraft) : 956  
Environmentally hazardous : yes

#### IMDG-Code

UN number : UN 3077  
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.  
(Mometasone)

Class : 9  
Packing group : III

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Labels : 9  
EmS Code : F-A, S-F  
Marine pollutant : yes

### Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

### Domestic regulation

#### NOM-002-SCT

UN number : UN 3077  
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,  
N.O.S.  
(Mometasone)  
Class : 9  
Packing group : III  
Labels : 9

### 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

Federal Law for the control of chemical precursors, essential chemical products and machinery for producing capsules, tablets and pills. : Not applicable

### The ingredients of this product are reported in the following inventories:

AICS : not determined  
DSL : not determined  
IECSC : not determined

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## SECTION 16. OTHER INFORMATION

Revision Date : 30.09.2023  
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### Full text of other abbreviations

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 Sys-

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tem; 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

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

The information is considered as correct, but not exhaustive, and will be used only as a guide, which is based in the current knowledge of the substance or mixture, and is applicable to proper safety precautions for the product.

MX / Z8