

# SAFETY DATA SHEET



## Lynestrenol Formulation



Version 4.1      Revision Date: 30.09.2023      SDS Number: 449554-00016      Date of last issue: 04.04.2023  
Date of first issue: 15.01.2016

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### SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Lynestrenol 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

Germ cell mutagenicity : Category 1B  
Carcinogenicity : Category 2  
Reproductive toxicity : Category 1A  
Specific target organ toxicity - repeated exposure : Category 1 (Blood, Mammary gland, Uterus (including cervix), Ovary)

#### GHS label elements

Hazard pictograms : 

Signal Word : Danger

Hazard Statements : H340 May cause genetic defects.  
H351 Suspected of causing cancer.  
H360Fd May damage fertility. Suspected of damaging the unborn child.  
H372 Causes damage to organs (Blood, Mammary gland, Uterus (including cervix), Ovary) through prolonged or repeated exposure.

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.  
P264 Wash skin thoroughly after handling.  
P270 Do not eat, drink or smoke when using this product.

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P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

**Response:**

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

**Storage:**

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)
Starch	9005-25-8	>= 20 -< 30
Lynestrenol	52-76-6	>= 5 -< 10
Talc	14807-96-6	>= 1 -< 5
Glycerine	56-81-5	>= 1 -< 5

### 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 cause genetic defects.  
Suspected of causing cancer.  
May damage fertility. Suspected of damaging the unborn child.

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Causes damage to organs through prolonged or repeated exposure.  
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.

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### SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media : Water spray  
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

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

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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.<br>Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.   |
| Local/Total ventilation     | : | If sufficient ventilation is unavailable, use with local exhaust ventilation.  |
| Advice on safe handling     | : | Do not get on skin or clothing.<br>Do not breathe dust.<br>Do not swallow.<br>Avoid contact with eyes.<br>Wash skin thoroughly after handling.<br>Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment<br>Keep container tightly closed.<br>Minimize dust generation and accumulation.<br>Keep container closed when not in use.<br>Keep away from heat and sources of ignition.<br>Take precautionary measures against static discharges.<br>Do not eat, drink or smoke when using this product.<br>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.<br>When using do not eat, drink or smoke.<br>Wash contaminated clothing before re-use.<br>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.<br>Store locked up.<br>Keep tightly closed.<br>Store in accordance with the particular national regulations.  |
| Materials to avoid          | : | Do not store with the following product types:<br>Strong oxidizing agents<br>Self-reactive substances and mixtures<br>Organic peroxides<br>Explosives<br>Gases   |

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**SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION****Ingredients with workplace control parameters**

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Starch	9005-25-8	VLE-PPT	10 mg/m <sup>3</sup>	NOM-010-STPS-2014
		TWA	10 mg/m <sup>3</sup>	ACGIH
Lynestrenol	52-76-6	TWA	1 µg/m <sup>3</sup> (OEB 4)	Internal
		Wipe limit	10 µg/100 cm <sup>2</sup>	Internal
Talc	14807-96-6	VLE-CT (Respirable fraction)	2 mg/m <sup>3</sup>	NOM-010-STPS-2014
		TWA (Respirable particulate matter)	2 mg/m <sup>3</sup>	ACGIH
Glycerine	56-81-5	VLE-PPT (Mist)	10 mg/m <sup>3</sup>	NOM-010-STPS-2014

**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.).  
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 : Combined particulates and organic vapor 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

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contaminated clothing.

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### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	powder
Color	:	No data available
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	:	Not applicable
Flammability (solid, gas)	:	May form explosive dust-air mixture during processing, handling or other means.
Flammability (liquids)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapor pressure	:	Not applicable
Relative vapor density	:	Not applicable
Relative density	:	No data available
Density	:	No data available
Solubility(ies) Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	Not applicable
Autoignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity Viscosity, kinematic	:	Not applicable
Explosive properties	:	Not explosive

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Oxidizing properties : The substance or mixture is not classified as oxidizing.  
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.

#### Product:

Acute oral toxicity : Acute toxicity estimate: > 5,000 mg/kg  
Method: Calculation method

#### Components:

##### Starch:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg  
Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg

##### Lynestrenol:

Acute oral toxicity : LD50: > 1,000 - 8,000 mg/kg  
Acute toxicity (other routes of administration) : LD50 (Mouse): 110 mg/kg  
Application Route: Intraperitoneal

##### Talc:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg  
Remarks: Based on data from similar materials

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### **Glycerine:**

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg

Acute dermal toxicity : LD50 (Guinea pig): > 5,000 mg/kg

### **Skin corrosion/irritation**

Not classified based on available information.

### **Components:**

#### **Talc:**

Species : Rabbit  
Result : No skin irritation

#### **Glycerine:**

Species : Rabbit  
Result : No skin irritation

### **Serious eye damage/eye irritation**

Not classified based on available information.

### **Components:**

#### **Starch:**

Species : Rabbit  
Result : No eye irritation

#### **Talc:**

Species : Rabbit  
Result : No eye irritation

#### **Glycerine:**

Species : Rabbit  
Result : No eye irritation

### **Respiratory or skin sensitization**

#### **Skin sensitization**

Not classified based on available information.

#### **Respiratory sensitization**

Not classified based on available information.

### **Components:**

#### **Starch:**

Test Type : Maximization Test  
Routes of exposure : Skin contact  
Species : Guinea pig  
Result : negative



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### Talc:

Routes of exposure : Skin contact  
Species : Humans  
Result : negative

### Germ cell mutagenicity

May cause genetic defects.

### Components:

#### Starch:

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

#### Lynestrenol:

Genotoxicity in vitro : Test Type: Chromosome aberration test in vitro  
Result: positive

Test Type: sister chromatid exchange assay  
Result: positive

Genotoxicity in vivo : Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)  
Species: Mouse  
Application Route: Intraperitoneal injection  
Result: positive

Test Type: sister chromatid exchange assay  
Species: Mouse  
Application Route: Intraperitoneal injection  
Result: positive

Test Type: dominant lethal test  
Species: Mouse  
Application Route: Intraperitoneal  
Result: positive

Germ cell mutagenicity - Assessment : Positive result(s) from in vivo somatic cell mutagenicity tests in mammals. Evidence that the substance has potential to cause mutations to germ cells

### Talc:

Genotoxicity in vitro : Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)  
Result: negative

Genotoxicity in vivo : Test Type: Chromosome aberration test in vitro  
Species: Rat  
Application Route: Ingestion  
Result: negative

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**Glycerine:**

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

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

Test Type: Chromosome aberration test in vitro  
Result: negative

Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)  
Result: negative

**Carcinogenicity**

Suspected of causing cancer.

**Components:****Lynestrenol:**

Species : Mouse  
Application Route : Oral  
Exposure time : 80 weeks  
Result : positive  
Tumor Type : breast tumors, Liver  
Remarks : Benign and malignant tumor(s)

Species : Rat  
Application Route : Oral  
Exposure time : 80 weeks  
Result : positive  
Tumor Type : breast tumors

Carcinogenicity - Assessment : Limited evidence of carcinogenicity in animal studies

**Talc:**

Species : Mouse  
Application Route : inhalation (dust/mist/fume)  
Exposure time : 2 Years  
Result : negative

**Glycerine:**

Species : Rat  
Application Route : Ingestion  
Exposure time : 2 Years  
Result : negative

**Reproductive toxicity**

May damage fertility. Suspected of damaging the unborn child.

**Components:****Lynestrenol:**

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Effects on fertility : Test Type: Fertility/early embryonic development  
Species: Rat, males  
Application Route: Oral  
Fertility: LOAEL: 20 mg/kg body weight  
Remarks: Impaired spermatogenesis

Test Type: Fertility/early embryonic development  
Species: Rat, females  
Application Route: Oral  
Fertility: LOAEL: 375 µg/kg  
Result: Maternal toxicity observed., Effects on fertility.

Test Type: Fertility/early embryonic development  
Species: Rabbit  
Application Route: Oral  
Fertility: LOAEL: 1,300 µg/kg  
Result: Effects on fertility., Postimplantation loss.

Effects on fetal development : Test Type: Embryo-fetal development  
Species: Rat  
Application Route: Oral  
Developmental Toxicity: LOAEL: 0.1 mg/kg body weight  
Result: Effects on fetal development.

Test Type: Embryo-fetal development  
Species: Rabbit  
Application Route: Oral  
Developmental Toxicity: LOAEL: 0.1 mg/kg body weight  
Result: Effects on fetal development., Postimplantation loss.

Reproductive toxicity - Assessment : Some evidence of adverse effects on development, based on animal experiments., Positive evidence of adverse effects on sexual function and fertility from human epidemiological studies.

### Talc:

Effects on fetal development : Test Type: Embryo-fetal development  
Species: Rat  
Application Route: Ingestion  
Result: negative

### Glycerine:

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

Effects on fetal development : Test Type: Embryo-fetal development  
Species: Rat  
Application Route: Ingestion  
Result: negative

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### STOT-single exposure

Not classified based on available information.

### STOT-repeated exposure

Causes damage to organs (Blood, Mammary gland, Uterus (including cervix), Ovary) through prolonged or repeated exposure.

### Components:

#### Lynestrenol:

Target Organs : Blood, Mammary gland, Uterus (including cervix), Ovary  
Assessment : Causes damage to organs through prolonged or repeated exposure.

### Repeated dose toxicity

### Components:

#### Starch:

Species : Rat  
NOAEL : >= 2,000 mg/kg  
Application Route : Skin contact  
Exposure time : 28 Days  
Method : OECD Test Guideline 410

#### Glycerine:

Species : Rat  
NOAEL : 0.167 mg/l  
LOAEL : 0.622 mg/l  
Application Route : inhalation (dust/mist/fume)  
Exposure time : 13 Weeks

Species : Rat  
NOAEL : 8,000 - 10,000 mg/kg  
Application Route : Ingestion  
Exposure time : 2 y

Species : Rabbit  
NOAEL : 5,040 mg/kg  
Application Route : Skin contact  
Exposure time : 45 Weeks

### Aspiration toxicity

Not classified based on available information.

### Experience with human exposure

### Components:

#### Lynestrenol:

Ingestion : Target Organs: Uterus (including cervix)  
Target Organs: breasts  
Target Organs: ovaries  
Target Organs: Blood

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Symptoms: Headache, Nausea, Abdominal pain, Rash, Dizziness, Tremors, Sweating, Vomiting, migraine, acne, breast tenderness, gynecomastia, menstrual irregularities, ovarian cysts

Remarks: Used to prevent pregnancy

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### SECTION 12. ECOLOGICAL INFORMATION

#### Ecotoxicity

##### Components:

##### **Talc:**

Toxicity to fish : LC50 (Brachydanio rerio (zebrafish)): > 100,000 mg/l  
Exposure time: 24 h

##### **Glycerine:**

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 54,000 mg/l  
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 1,955 mg/l  
Exposure time: 48 h

Toxicity to microorganisms : NOEC (Pseudomonas putida): > 10,000 mg/l  
Exposure time: 16 h  
Method: DIN 38 412 Part 8

#### Persistence and degradability

##### Components:

##### **Glycerine:**

Biodegradability : Result: Readily biodegradable.  
Biodegradation: 92 %  
Exposure time: 30 d  
Method: OECD Test Guideline 301D

#### Bioaccumulative potential

##### Components:

##### **Glycerine:**

Partition coefficient: n-octanol/water : log Pow: -1.75

##### **Mobility in soil**

No data available

##### **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

Not regulated as a dangerous good

##### IATA-DGR

Not regulated as a dangerous good

##### IMDG-Code

Not regulated as a dangerous good

#### 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

Not regulated as a dangerous good

#### Special precautions for user

Not applicable

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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

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### Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)  
NOM-010-STPS-2014 : Mexico. Norm NOM-010-STPS-2014 on Chemicals Polluting the Work Environment - Identification, Assessment and Control - Appendix 1 Occupational Exposure Limits  
ACGIH / TWA : 8-hour, time-weighted average  
NOM-010-STPS-2014 / VLE- : Time weighted average limit value  
PPT  
NOM-010-STPS-2014 / VLE- : Short term exposure limit value  
CT

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; TECl - 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