

# SAFETY DATA SHEET



## Desogestrel Formulation



Version 4.4      Revision Date: 16.10.2020      SDS Number: 21973-00019      Date of last issue: 23.03.2020  
Date of first issue: 15.10.2014

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### 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Desogestrel 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

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### 2. HAZARDS IDENTIFICATION

#### Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

##### Classification

Not classified as hazardous according to criteria laid down in Part I of Schedule-1.



##### GHS Classification

Reproductive toxicity : Category 1B

Specific target organ toxicity - repeated exposure : Category 1 (Pituitary gland, Uterus (including cervix), Ovary, Mammary gland, Prostate)

Long-term (chronic) aquatic hazard : Category 1

##### GHS label elements

Hazard pictograms :  

Signal word : Danger

Hazard statements : H360Fd May damage fertility. Suspected of damaging the unborn child.  
H372 Causes damage to organs (Pituitary gland, Uterus (including cervix), Ovary, Mammary gland, Prostate) through prolonged or repeated exposure.  
H410 Very toxic to aquatic life with long lasting effects.

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Precautionary statements : **Prevention:**  
P203 Obtain, read and follow all safety instructions before use.  
P260 Do not breathe dust.  
P264 Wash skin thoroughly after handling.  
P270 Do not eat, drink or smoke when using this product.  
P273 Avoid release to the environment.  
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

**Response:**  
P318 IF exposed or concerned, get medical advice.  
P391 Collect spillage.

**Storage:**  
P405 Store locked up.

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

**Other hazards which do not result in classification**

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.

**3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture : Mixture

**Components**

Chemical name	CAS-No.	Concentration (% w/w)
Titanium dioxide	13463-67-7	$\geq 0.1 - < 1$
Desogestrel	54024-22-5	$\geq 0.1 - < 0.25$

**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.

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Most important symptoms and effects, both acute and delayed	:	Rinse mouth thoroughly with water. May damage fertility. Suspected of damaging the unborn child. Causes damage to organs through prolonged or repeated exposure. Contact with dust can cause mechanical irritation or drying of the skin.
Protection of first-aiders	:	Dust contact with the eyes can lead to mechanical irritation. 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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**5. FIREFIGHTING 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 Nitrogen oxides (NO <sub>x</sub> )
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 firefighters	:	In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

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**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 surfac-

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es, 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.

## 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.
- 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.  
Wash skin thoroughly after handling.  
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.  
Do not eat, drink or smoke when using this product.  
Take care to prevent spills, waste and minimize release to the environment.
- Conditions for safe storage : Keep in properly labelled 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

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Titanium dioxide	13463-67-7	TWA	10 mg/m <sup>3</sup> (Titanium dioxide)	ACGIH
Desogestrel	54024-22-5	TWA	0.04 µg/m <sup>3</sup> (OEB 5)	Internal
		Wipe limit	0.4 µg/100 cm <sup>2</sup>	Internal

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- Engineering measures** : Use closed processing systems or containment technologies to control at source (e.g., glove boxes/isolators) and to prevent leakage of compounds into the workplace.  
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.  
No open handling permitted.  
Totally enclosed processes and materials transport systems are required.  
Operations require the use of appropriate containment technology designed to prevent leakage of compounds into the workplace.
- 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.
- 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.

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**9. PHYSICAL AND CHEMICAL PROPERTIES**

- Appearance : powder
- Colour : white
- Odour : No data available
- Odour Threshold : No data available

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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
Vapour pressure	:	Not applicable
Relative vapour 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
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity Viscosity, kinematic	:	Not applicable
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Particle size	:	No data available

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### 10. STABILITY AND REACTIVITY

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.

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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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**11. TOXICOLOGICAL INFORMATION**

Information on likely routes of exposure : Inhalation  
Skin contact  
Ingestion  
Eye contact

**Acute toxicity**

Not classified based on available information.

**Components:****Titanium dioxide:**

Acute oral toxicity	:	LD50 (Rat): > 5,000 mg/kg
Acute inhalation toxicity	:	LC50 (Rat): > 6.82 mg/l Exposure time: 4 h Test atmosphere: dust/mist Assessment: The substance or mixture has no acute inhalation toxicity

**Desogestrel:**

Acute oral toxicity	:	LD50 (Rat, male and female): > 2,000 mg/kg  LD50 (Mouse, male and female): > 2,000 mg/kg
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**Skin corrosion/irritation**

Not classified based on available information.

**Components:****Titanium dioxide:**

Species	:	Rabbit
Result	:	No skin irritation

**Serious eye damage/eye irritation**

Not classified based on available information.

**Components:****Titanium dioxide:**

Species	:	Rabbit
Result	:	No eye irritation

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**Respiratory or skin sensitisation****Skin sensitisation**

Not classified based on available information.

**Respiratory sensitisation**

Not classified based on available information.

**Components:****Titanium dioxide:**

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

**Germ cell mutagenicity**

Not classified based on available information.

**Components:****Titanium dioxide:**

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative  
  
Genotoxicity in vivo : Test Type: In vivo micronucleus test  
Species: Mouse  
Result: negative

**Desogestrel:**

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative  
  
Genotoxicity in vivo : Test Type: Micronucleus test  
Species: Rat  
Application Route: Intraperitoneal  
Result: negative

**Carcinogenicity**

Not classified based on available information.

**Components:****Titanium dioxide:**

Species : Rat  
Application Route : inhalation (dust/mist/fume)  
Exposure time : 2 Years  
Method : OECD Test Guideline 453  
Result : positive  
Remarks : The mechanism or mode of action may not be relevant in humans.

Carcinogenicity - Assess- : Limited evidence of carcinogenicity in inhalation studies with



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ment animals.

**Desogestrel:**

Species : Rat  
 Application Route : Oral  
 Exposure time : 104 weeks  
 Result : negative

Species : Mouse  
 Application Route : Oral  
 Exposure time : 81 weeks  
 Result : negative

**Reproductive toxicity**

May damage fertility. Suspected of damaging the unborn child.

**Components:****Desogestrel:**

Effects on fertility : Test Type: Fertility/early embryonic development  
 Species: Rabbit, female  
 Fertility: LOAEL Parent: 2 mg/kg body weight  
 Result: Effects on fertility

Test Type: Fertility/early embryonic development  
 Species: Rat, female  
 Fertility: NOAEL Parent: 0.5 mg/kg body weight  
 Result: No effects on fertility

Effects on foetal development : Test Type: Embryo-foetal development  
 Species: Rabbit, female  
 Application Route: Oral  
 Developmental Toxicity: NOAEL F1: 1 mg/kg body weight  
 Result: Embryotoxic effects and adverse effects on the offspring were detected., No teratogenic effects

Test Type: Embryo-foetal development  
 Species: Rat, female  
 Application Route: Oral  
 Embryo-foetal toxicity: LOAEC Parent: 0.125 mg/kg body weight  
 Result: No teratogenic effects

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

**STOT - single exposure**

Not classified based on available information.

**STOT - repeated exposure**

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

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**Components:****Desogestrel:**

Target Organs : Pituitary gland, Uterus (including cervix), Ovary, Mammary gland, Prostate

Assessment : Causes damage to organs through prolonged or repeated exposure.

**Repeated dose toxicity****Components:****Titanium dioxide:**

Species : Rat

NOAEL : 24,000 mg/kg

Application Route : Ingestion

Exposure time : 28 Days

Species : Rat

NOAEL : 10 mg/m<sup>3</sup>

Application Route : inhalation (dust/mist/fume)

Exposure time : 2 yr

**Desogestrel:**

Species : Rat, female

LOAEL : 0.00625 mg/kg

Application Route : Oral

Exposure time : 26 Weeks

Target Organs : Pituitary gland, Uterus (including cervix), Ovary, Mammary gland

Species : Rat

LOAEL : 0.005 mg/kg

Application Route : Oral

Exposure time : 52 Weeks

Target Organs : Pituitary gland, Uterus (including cervix), Ovary, Mammary gland

Species : Dog

LOAEL : 0.005 mg/kg

Application Route : Oral

Exposure time : 52 Weeks

Target Organs : Pituitary gland, Uterus (including cervix), Ovary, Mammary gland, Prostate

**Aspiration toxicity**

Not classified based on available information.

**Experience with human exposure****Components:****Desogestrel:**

Ingestion : Symptoms: Headache, changes in libido, Dizziness, Nausea,

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Vomiting, Diarrhoea, water retention, sodium retention, Gastrointestinal discomfort, mental depression, amenorhea, insomnia, impaired glucose tolerance, pulmonary embolism  
 Target Organs: Uterus (including cervix)  
 Target Organs: Mammary gland

**12. ECOLOGICAL INFORMATION****Ecotoxicity****Components:****Titanium dioxide:**

- Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l  
 Exposure time: 96 h  
 Method: OECD Test Guideline 203
- Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 100 mg/l  
 Exposure time: 48 h
- Toxicity to algae/aquatic plants : EC50 ( Skeletonema costatum (marine diatom)): > 10,000 mg/l  
 Exposure time: 72 h
- Toxicity to microorganisms : EC50: > 1,000 mg/l  
 Exposure time: 3 h  
 Method: OECD Test Guideline 209

**Desogestrel:**

- Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 4 mg/l  
 Exposure time: 96 h  
 Method: FDA 4.11  
 Remarks: Based on data from similar materials
- LC50 (Lepomis macrochirus (Bluegill sunfish)): 1.3 mg/l  
 Exposure time: 96 h  
 Method: OECD Test Guideline 203  
 Remarks: No toxicity at the limit of solubility  
 Based on data from similar materials
- Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 3.9 mg/l  
 Exposure time: 48 h  
 Method: OECD Test Guideline 202  
 Remarks: No toxicity at the limit of solubility  
 Based on data from similar materials
- Toxicity to microorganisms : EC50: > 1,000 mg/l  
 Exposure time: 3 h  
 Test Type: Respiration inhibition  
 Method: OECD Test Guideline 209  
 Remarks: Based on data from similar materials
- NOEC: 70.8 mg/l  
 Exposure time: 3 h

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Test Type: Respiration inhibition  
Remarks: Based on data from similar materials

Toxicity to fish (Chronic toxicity) : NOEC: 0.059 mg/l  
Exposure time: 32 d  
Species: Pimephales promelas (fathead minnow)  
Method: OECD Test Guideline 210  
Remarks: Based on data from similar materials

NOEC: 0.0000027 mg/l  
Exposure time: 183 d  
Species: Oryzias latipes (Japanese medaka)  
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 1.2 mg/l  
Exposure time: 21 d  
Species: Daphnia magna (Water flea)  
Remarks: Based on data from similar materials

M-Factor (Chronic aquatic toxicity) : 10,000

### Persistence and degradability

#### Components:

##### **Desogestrel:**

Stability in water : Hydrolysis: < 10 %(5 d)  
Remarks: Based on data from similar materials

### Bioaccumulative potential

#### Components:

##### **Desogestrel:**

Bioaccumulation : Species: Lepomis macrochirus (Bluegill sunfish)  
Bioconcentration factor (BCF): 128  
Remarks: Based on data from similar materials

Partition coefficient: n-octanol/water : log Pow: 3.5

### Mobility in soil

#### Components:

##### **Desogestrel:**

Distribution among environmental compartments : log Koc: 2.84

### Other adverse effects

No data available

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**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 handling site for recycling or disposal.  
If not otherwise specified: Dispose of as unused product.

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**14. TRANSPORT INFORMATION****International Regulations****UNRTDG**

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

**IATA-DGR**

UN/ID No. : UN 3077  
Proper shipping name : Environmentally hazardous substance, solid, n.o.s. (Desogestrel)  
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. (Desogestrel)  
Class : 9  
Packing group : III  
Labels : 9  
EmS Code : F-A, S-F  
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.

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**15. REGULATORY INFORMATION****Safety, health and environmental regulations/legislation specific for the substance or mixture****The components of this product are reported in the following inventories:**

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

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**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)

ACGIH / TWA : 8-hour, 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 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 - Trans-

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portation 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.

IN / EN