# **Desogestrel Formulation**



 Version
 Revision Date:
 SDS Number:
 Date of last issue: 2020/10/16

 4.8
 2021/04/09
 21970-00020
 Date of first issue: 2014/10/15

#### 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Desogestrel Formulation

Manufacturer or supplier's details

Company : Organon & Co.

Address : JL Raya Pandaan KM. 48

Pandaan, Jawa Timur - Indonesia

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

#### 2. HAZARDS IDENTIFICATION

**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 un-

born child.

H372 Causes damage to organs (Pituitary gland, Uterus (including cervix), Ovary, Mammary gland, Prostate) through pro-

longed or repeated exposure.

H410 Very toxic to aquatic life with long lasting effects.

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.

# **Desogestrel Formulation**



Version **Revision Date:** SDS Number: Date of last issue: 2020/10/16 2021/04/09 21970-00020 Date of first issue: 2014/10/15 4.8

P270 Do not eat, drink or smoke when using this product.

P273 Avoid release to the environment.

P280 Wear protective gloves/ protective clothing/ eye protec-

tion/ face protection.

Response:

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

attention.

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	< 1
Desogestrel	54024-22-5	>= 0.025 -< 0.25

#### 4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical ad-

vice immediately.

When symptoms persist or in all cases of doubt seek medical

advice.

If inhaled If inhaled, remove to fresh air.

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 fertility. Suspected of damaging the unborn

child.

Causes damage to organs through prolonged or repeated

# **Desogestrel Formulation**



Version Revision Date: SDS Number: Date of last issue: 2020/10/16
4.8 2021/04/09 21970-00020 Date of first issue: 2014/10/15

exposure.

Contact with dust can cause mechanical irritation or drying of

the skin.

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.

#### 5. FIREFIGHTING MEASURES

Protection of first-aiders

Suitable extinguishing media : Water spray

Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical None known.

Unsuitable extinguishing

media

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 prod-

ucts

Carbon oxides

Nitrogen oxides (NOx)

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances 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.

### 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emer-

gency procedures

Use personal protective equipment.

Follow safe handling advice (see section 7) and personal pro-

tective 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 con-

tainer 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





Version Revision Date: SDS Number: Date of last issue: 2020/10/16 4.8 2021/04/09 21970-00020 Date of first issue: 2014/10/15

employed in the cleanup of releases. You will need to deter-

mine 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 as-

sessment

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	Control parame- ters / Permissible	Basis	
		`			
		exposure)	concentration		
Titanium dioxide	13463-67-7	NAB	10 mg/m3	ID OEL	
	Further information: Not classified as carcinogenic to humans. Not				
	enough data to classify these materials as carcinogenic to hu-				
	mans or animals				
		TWA	10 mg/m3	ACGIH	
			(Titanium dioxide)		
Desogestrel	54024-22-5	TWA	0.04 µg/m3 (OEB	Internal	
			5)		
		Wipe limit	0.4 μg/100 cm <sup>2</sup>	Internal	





Version **Revision Date:** SDS Number: Date of last issue: 2020/10/16 2021/04/09 21970-00020 Date of first issue: 2014/10/15 4.8

**Engineering measures** Use closed processing systems or containment technologies

to control at source (e.g., glove boxes/isolators) and to pre-

vent 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 expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

Filter type

Hand protection

Particulates type

Material Chemical-resistant gloves

Consider double gloving. Remarks

Wear safety glasses with side shields or goggles. Eye protection

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.

Work uniform or laboratory coat. Skin and body protection

> Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, dis-

posable suits) to avoid exposed skin surfaces.

Use appropriate degowning techniques to remove potentially

contaminated clothing.

If exposure to chemical is likely during typical use, provide Hygiene measures

eye flushing systems and safety showers close to the work-

ing 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.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance powder

Colour white

Odour No data available

Odour Threshold No data available





Version Revision Date: SDS Number: Date of last issue: 2020/10/16
4.8 2021/04/09 21970-00020 Date of first issue: 2014/10/15

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, han-

dling 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

# 10. STABILITY AND REACTIVITY

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



# **Desogestrel Formulation**

Version Revision Date: SDS Number: Date of last issue: 2020/10/16
4.8 2021/04/09 21970-00020 Date of first issue: 2014/10/15

Possibility of hazardous reac-

tions

May form explosive dust-air mixture during processing, han-

dling or other means.

Can react with strong oxidizing agents.

Conditions to avoid : Heat, flames and sparks.

Avoid dust formation. Oxidizing agents

Incompatible materials

Hazardous decomposition

products

No hazardous decomposition products are known.

#### 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 inhala-

tion toxicity

Desogestrel:

Acute oral toxicity : LD50 (Rat, male and female): > 2,000 mg/kg

LD50 (Mouse, male and female): > 2,000 mg/kg

#### 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

# **Desogestrel Formulation**



Version Revision Date: SDS Number: Date of last issue: 2020/10/16 4.8 2021/04/09 21970-00020 Date of first issue: 2014/10/15

## 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 hu-

mans.

Carcinogenicity - Assess-

ment

Limited evidence of carcinogenicity in inhalation studies with

animals.

# **Desogestrel Formulation**



 Version
 Revision Date:
 SDS Number:
 Date of last issue: 2020/10/16

 4.8
 2021/04/09
 21970-00020
 Date of first issue: 2014/10/15

**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 develop-

ment

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 off-

spring 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 - As-

sessment

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.



# **Desogestrel Formulation**

**╬** ORGANON

Version Revision Date: SDS Number: Date of last issue: 2020/10/16
4.8 2021/04/09 21970-00020 Date of first issue: 2014/10/15

**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/m3

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,





Version Revision Date: SDS Number: Date of last issue: 2020/10/16 4.8 2021/04/09 21970-00020 Date of first issue: 2014/10/15

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 fish (Chronic tox-

icity)

NOEC (Pimephales promelas (fathead minnow)): 0.059 mg/l

Exposure time: 32 d

Method: OECD Test Guideline 210

Remarks: Based on data from similar materials

NOEC (Oryzias latipes (Japanese medaka)): 0.0000027 mg/l

Exposure time: 183 d

Remarks: Based on data from similar materials





Version **Revision Date:** SDS Number: Date of last issue: 2020/10/16 2021/04/09 21970-00020 Date of first issue: 2014/10/15 4.8

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Toxicity to daphnia and other :

aquatic invertebrates (Chron-

ic toxicity)

NOEC (Daphnia magna (Water flea)): 1.2 mg/l

Exposure time: 21 d

Remarks: Based on data from similar materials

M-Factor (Chronic aquatic

toxicity)

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

Test Type: Respiration inhibition

Remarks: Based on data from similar materials

### Persistence and degradability

#### **Components:**

Desogestrel:

Stability in water Hydrolysis: < 10 %(5 d)

Remarks: Based on data from similar materials

#### Bioaccumulative potential

# **Components:**

Desogestrel:

Species: Lepomis macrochirus (Bluegill sunfish) Bioaccumulation

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 environ-

mental compartments

log Koc: 2.84

### Other adverse effects

No data available

#### 13. DISPOSAL CONSIDERATIONS

#### Disposal methods

Waste from residues Dispose of in accordance with local regulations.

Empty containers should be taken to an approved waste han-Contaminated packaging

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

# **Desogestrel Formulation**



Version **Revision Date:** SDS Number: Date of last issue: 2020/10/16 2021/04/09 21970-00020 Date of first issue: 2014/10/15 4.8

#### 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 Ш Labels 9

**IATA-DGR** 

**UN 3077** UN/ID No.

Proper shipping name Environmentally hazardous substance, solid, n.o.s.

(Desogestrel)

Class Packing group Ш

Labels Miscellaneous

Packing instruction (cargo 956

aircraft)

Packing instruction (passen-

ger aircraft)

956

Environmentally hazardous yes

**IMDG-Code** 

**UN** number UN 3077

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, Proper shipping name

N.O.S.

(Desogestrel)

Class 9 Ш Packing group 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.

#### 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.

#### 15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture

# **Desogestrel Formulation**



Version Revision Date: SDS Number: Date of last issue: 2020/10/16 4.8 2021/04/09 21970-00020 Date of first issue: 2014/10/15

Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.

Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health

Hazardous substances that must be registered : Not applicable

Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances

Hazardous substances approved for use : Not applicable

Prohibited substances : Not applicable

Restricted substances : Not applicable

Regulation of the Minister of Trade No. 44 of 2009 on Procurement, Distribution and Supervision of Hazardous Materials

Type of Hazardous Materials Restricted to Import, : Not applicable

Distribution and Supervision

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

AICS : not determined

DSL : not determined

IECSC : not determined

#### 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 Agen-

cy, http://echa.europa.eu/

Date format : yyyy/mm/dd

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
ID OEL : Indonesia. Occupational Exposure Limits

ACGIH / TWA : 8-hour, time-weighted average ID OEL / NAB : Long term exposure limit

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with

# **Desogestrel Formulation**



Version Revision Date: SDS Number: Date of last issue: 2020/10/16 4.8 2021/04/09 21970-00020 Date of first issue: 2014/10/15

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; 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.

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