according to Regulation (EC) No. 1907/2006



## **Desogestrel Formulation**

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#### SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

**Desogestrel Formulation** Trade name

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Sub-: Pharmaceutical

stance/Mixture

1.3 Details of the supplier of the safety data sheet

Company Organon & Co.

Shotton Lane

NE23 3JU Cramlington NU - Great Britain

44 1 670 59 30 00 Telephone

E-mail address of person responsible for the SDS

: EHSSTEWARD@organon.com

1.4 Emergency telephone number

215-631-6999

#### **SECTION 2: Hazards identification**

#### 2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Reproductive toxicity, Category 1B H360Fd: May damage fertility. Suspected of dam-

aging the unborn child.

H372: Causes damage to organs through pro-Specific target organ toxicity - repeated

exposure, Category 1 longed or repeated exposure.

Long-term (chronic) aquatic hazard, Cat-H410: Very toxic to aquatic life with long lasting

egory 1

2.2 Label elements

Signal word

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms

Danger

Hazard statements H360Fd May damage fertility. Suspected of damaging

the unborn child.

H372 Causes damage to organs through prolonged or re-

peated exposure.

H410 Very toxic to aquatic life with long lasting effects.

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Precautionary statements : Prevention:

P201 Obtain special instructions before use.

P260 Do not breathe dust.

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.

#### Hazardous components which must be listed on the label:

Desogestrel

#### 2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

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**

#### 3.2 Mixtures

Components

Chemical name	CAS-No. EC-No. Index-No.	Classification	Concentration (% w/w)
Desogestrel	Registration number 54024-22-5 258-929-4	Repr. 1B; H360Fd STOT RE 1; H372 (Pituitary gland, Uter- us (including cervix), Ovary, Mammary gland, Prostate) Aquatic Chronic 1; H410	>= 0.1 - < 0.25
		M-Factor (Chronic aquatic toxicity): 10,000	

For explanation of abbreviations see section 16.

#### **SECTION 4: First aid measures**

#### 4.1 Description of first aid measures

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

according to Regulation (EC) No. 1907/2006



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vice immediately.

When symptoms persist or in all cases of doubt seek medical

advice.

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).

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.

#### 4.2 Most important symptoms and effects, both acute and delayed

Risks : 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.

Dust contact with the eyes can lead to mechanical irritation.

#### 4.3 Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically and supportively.

#### **SECTION 5: Firefighting measures**

#### 5.1 Extinguishing media

Suitable extinguishing media : Water spray

Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

: None known.

according to Regulation (EC) No. 1907/2006



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#### 5.2 Special hazards arising from the substance or mixture

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)

#### 5.3 Advice for firefighters

Special protective equipment:

for firefighters

In the event of fire, wear self-contained breathing apparatus.

Use personal protective equipment.

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.

#### **SECTION 6: Accidental release measures**

#### 6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment.

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

tective equipment recommendations (see section 8).

#### 6.2 Environmental precautions

Environmental precautions : Avoid rele

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.

#### 6.3 Methods and material for containment and cleaning up

Methods for 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 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.

according to Regulation (EC) No. 1907/2006



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6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

**SECTION 7: Handling and storage** 

7.1 Precautions for safe handling

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.

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 contami-

nated 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.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers

Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national

regulations.

Do not store with the following product types: Advice on common storage

> Strong oxidizing agents Organic peroxides

**Explosives** Gases

7.3 Specific end use(s)

Specific use(s) No data available

according to Regulation (EC) No. 1907/2006



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#### **SECTION 8: Exposure controls/personal protection**

#### 8.1 Control parameters

#### **Occupational Exposure Limits**

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis	
Starch, oxidized	65996-62-5	TWA (inhalable dust)	10 mg/m3	GB EH40	
	Further information: Capable of causing occupational asthma.				
		STEL (inhalable dust)	30 mg/m3	GB EH40	
	Further information: Capable of causing occupational asthma.				
Desogestrel	54024-22-5	TWA	0.04 μg/m3 (OEB 5)	Internal	
		Wipe limit	0.4 μg/100 cm <sup>2</sup>	Internal	

#### 8.2 Exposure controls

#### **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

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.

Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

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, dis-

posable suits) to avoid exposed skin surfaces.

Use appropriate degowning techniques to remove potentially

contaminated clothing.

Respiratory protection : If adequate local exhaust ventilation is not available or expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

Equipment should conform to BS EN 143

Filter type : Particulates type (P)

according to Regulation (EC) No. 1907/2006



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#### **SECTION 9: Physical and chemical properties**

9.1 Information on basic physical and chemical properties

Appearance : powder Colour : white

Odour : No data available
Odour 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, 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- : Not applicable

octanol/water

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.

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# Public → ORGANON

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9.2 Other information

Particle size : No data available

## **SECTION 10: Stability and reactivity**

#### 10.1 Reactivity

Not classified as a reactivity hazard.

#### 10.2 Chemical stability

Stable under normal conditions.

#### 10.3 Possibility of hazardous reactions

Hazardous reactions : May form explosive dust-air mixture during processing, han-

dling or other means.

Can react with strong oxidizing agents.

10.4 Conditions to avoid

Conditions to avoid : Heat, flames and sparks.

Avoid dust formation.

10.5 Incompatible materials

Materials to avoid : Oxidizing agents

#### 10.6 Hazardous decomposition products

No hazardous decomposition products are known.

#### **SECTION 11: Toxicological information**

#### 11.1 Information on toxicological effects

Information on likely routes of : Inhalation

exposure Skin contact

Ingestion Eye contact

#### **Acute toxicity**

Not classified based on available information.

#### **Components:**

#### **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.

#### Serious eye damage/eye irritation

Not classified based on available information.

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#### Respiratory or skin sensitisation

#### Skin sensitisation

Not classified based on available information.

#### Respiratory sensitisation

Not classified based on available information.

#### Germ cell mutagenicity

Not classified based on available information.

#### **Components:**

#### **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:**

#### 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

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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 through prolonged or repeated exposure.

#### 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:**

#### 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

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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,

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

**SECTION 12: Ecological information** 

12.1 Toxicity

Components:

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

Test Type: Respiration inhibition

Remarks: Based on data from similar materials

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Toxicity to fish (Chronic tox-

icity)

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 (Chron-

ic 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

#### 12.2 Persistence and degradability

#### **Components:**

**Desogestrel:** 

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

Remarks: Based on data from similar materials

#### 12.3 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

#### 12.4 Mobility in soil

#### **Components:**

**Desogestrel:** 

Distribution among environ-

mental compartments

: log Koc: 2.84

#### 12.5 Results of PBT and vPvB assessment

#### **Product:**

Assessment : This substance/mixture contains no components considered

to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of

0.1% or higher.

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#### 12.6 Other adverse effects

**Product:** 

Endocrine disrupting poten-

tial

The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at

levels of 0.1% or higher.

#### **SECTION 13: Disposal considerations**

#### 13.1 Waste treatment methods

Product : Dispose of in accordance with local regulations.

According to the European Waste Catalogue, Waste Codes

are not product specific, but application specific.

Waste codes should be assigned by the user, preferably in

discussion with the waste disposal authorities.

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

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

### **SECTION 14: Transport information**

#### 14.1 UN number

ADN : UN 3077
ADR : UN 3077
RID : UN 3077
IMDG : UN 3077
IATA : UN 3077

#### 14.2 UN proper shipping name

**ADN** : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

(Desogestrel)

ADR : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

(Desogestrel)

RID : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

(Desogestrel)

IMDG : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

(Desogestrel)

**IATA** : Environmentally hazardous substance, solid, n.o.s.

(Desogestrel)

#### 14.3 Transport hazard class(es)

according to Regulation (EC) No. 1907/2006



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 ADN
 : 9

 ADR
 : 9

 RID
 : 9

 IMDG
 : 9

 IATA
 : 9

#### 14.4 Packing group

**ADN** 

Packing group : III
Classification Code : M7
Hazard Identification Number : 90
Labels : 9

**ADR** 

Packing group : III
Classification Code : M7
Hazard Identification Number : 90
Labels : 9
Tunnel restriction code : (-)

**RID** 

Packing group : III
Classification Code : M7
Hazard Identification Number : 90
Labels : 9

**IMDG** 

Packing group : III Labels : 9

EmS Code : F-A, S-F

IATA (Cargo)

Packing instruction (cargo : 956

aircraft)

Packing instruction (LQ) : Y956
Packing group : III

Labels : Miscellaneous

IATA (Passenger)

Packing instruction (passen: 956

ger aircraft)

Packing instruction (LQ) : Y956
Packing group : III

Labels : Miscellaneous

14.5 Environmental hazards

**ADN** 

Environmentally hazardous : yes

ADR

Environmentally hazardous : yes

rid

Environmentally hazardous : yes

according to Regulation (EC) No. 1907/2006



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**IMDG** 

Marine pollutant : yes

IATA (Passenger)

Environmentally hazardous : yes

IATA (Cargo)

Environmentally hazardous : yes

#### 14.6 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.

#### 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Remarks : Not applicable for product as supplied.

#### **SECTION 15: Regulatory information**

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

Not applicable

Not applicable

Not applicable

Not applicable

Not applicable

Not applicable

Quantity 2

REACH - Restrictions on the manufacture, placing on

the market and use of certain dangerous substances,

preparations and articles (Annex XVII)

REACH - Candidate List of Substances of Very High

Concern for Authorisation (Article 59).

REACH - List of substances subject to authorisation

(Annex XIV)

Regulation (EC) No 1005/2009 on substances that de-

plete the ozone layer

Regulation (EU) 2019/1021 on persistent organic pollu-

tants (recast)

Regulation (EC) No 649/2012 of the European Parlia-

ment and the Council concerning the export and import

of dangerous chemicals

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of

major-accident hazards involving dangerous substances.

Quantity 1

E1 ENVIRONMENTAL 100 t 200 t

**HAZARDS** 

#### Other regulations:

Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.

Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

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

AICS : not determined

DSL : not determined

IECSC : not determined

according to Regulation (EC) No. 1907/2006



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#### 15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

#### **SECTION 16: Other information**

Other information : Items where changes have been made to the previous version

are highlighted in the body of this document by two vertical

lines.

**Full text of H-Statements** 

H360Fd : May damage fertility. Suspected of damaging the unborn

child

H372 : Causes damage to organs through prolonged or repeated

exposure.

H410 : Very toxic to aquatic life with long lasting effects.

Full text of other abbreviations

Aquatic Chronic : Long-term (chronic) aquatic hazard

Repr. : Reproductive toxicity

STOT RE : Specific target organ toxicity - repeated exposure GB EH40 : UK. EH40 WEL - Workplace Exposure Limits

GB EH40 / TWA : Long-term exposure limit (8-hour TWA reference period)
GB EH40 / STEL : Short-term exposure limit (15-minute reference period)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road: AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant: DIN -Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TRGS -

according to Regulation (EC) No. 1907/2006



## **Desogestrel Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 16.10.2020

 5.5
 09.04.2021
 21969-00020
 Date of first issue: 15.10.2014

Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

#### **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/

#### Classification of the mixture: Classification procedure:

Repr. 1B H360Fd Calculation method STOT RE 1 H372 Calculation method Aquatic Chronic 1 H410 Calculation method

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.

GB / EN