Desogestrel Formulation



Version Revision Date: SDS Number: Date of last issue: 2020/03/23 7.1 2020/10/16 21976-00019 Date of first issue: 2014/10/15

1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Desogestrel Formulation

Supplier's company name, address and phone number

Company name of supplier : Organon & Co.

Address : 30 Hudson Street, 33nd floor

Jersey City, New Jersey, U.S.A 07302

Telephone : 551-430-6000

E-mail address : EHSSTEWARD@organon.com

Emergency telephone number : 215-631-6999

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

2. HAZARDS IDENTIFICATION

GHS classification of chemical product

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: 2020/03/23 7.1 2020/10/16 21976-00019 Date of first issue: 2014/10/15

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

Important symptoms and outlines of the emergency assumed :

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)	ENCS No.
Propylene glycol	57-55-6	>= 0.1 - < 1	2-234
Titanium dioxide	13463-67-7	>= 0.1 - < 1	1-558, 5-5225
Desogestrel	54024-22-5	>= 0.1 - < 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.





Version Revision Date: SDS Number: Date of last issue: 2020/03/23 7.1 2020/10/16 21976-00019 Date of first issue: 2014/10/15

If swallowed, DO NOT induce vomiting.

Get medical attention.

Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and

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. 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).

: Treat symptomatically and supportively.

5. FIREFIGHTING MEASURES

Notes to physician

Protection of first-aiders

Suitable extinguishing media : Water spray

Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

delayed

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 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, protec- :

tive equipment and emergency 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

Desogestrel Formulation



Version Revision Date: SDS Number: Date of last issue: 2020/03/23 7.1 2020/10/16 21976-00019 Date of first issue: 2014/10/15

with compressed air).

Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

7. HANDLING AND STORAGE

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.

Avoidance of contact

Oxidizing agents

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.

Storage

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:

Desogestrel Formulation



Version Revision Date: SDS Number: Date of last issue: 2020/03/23 7.1 2020/10/16 21976-00019 Date of first issue: 2014/10/15

Strong oxidizing agents

Packaging material : Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Threshold limit value and permissible exposure limits for each component in the work environment

Components	CAS-No.	Value type (Form of	Control parame- ters / Permissible	Basis	
		exposure)	concentration		
Titanium dioxide	13463-67-7	OEL-M	1 mg/m3	JP OEL	
		(Respirable	(Titanium)	JSOH	
		dust)			
	Further information: Class 2 Dust		ust		
		OEL-M (Total	4 mg/m3	JP OEL	
		dust)	(Titanium)	JSOH	
	Further information: Class 2 Dust				
		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 ²	Internal	

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

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.

Desogestrel Formulation



Version Revision Date: SDS Number: Date of last issue: 2020/03/23 7.1 2020/10/16 21976-00019 Date of first issue: 2014/10/15

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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state : powder

Colour : white

Odour : No data available

Odour Threshold : No data available

Melting point/freezing point : No data available

Boiling point, initial boiling

point and boiling range

No data available

Flammability (solid, gas) : May form explosive dust-air mixture during processing, han-

dling or other means.

Flammability (liquids) : No data available

Lower explosion limit and upper explosion limit / flammability limit

Upper explosion limit / Upper :

flammability limit

No data available

Lower explosion limit / Lower

flammability limit

No data available

Flash point : Not applicable

Decomposition temperature : No data available

pH : No data available

Evaporation rate : Not applicable

Auto-ignition temperature : No data available

Viscosity

Viscosity, kinematic : Not applicable

Solubility(ies)

Water solubility : No data available

Partition coefficient: n-

octanol/water

: Not applicable

Vapour pressure : Not applicable

Density and / or relative density



Public

Desogestrel Formulation

♣ ORGANON

Version Revision Date: SDS Number: Date of last issue: 2020/03/23 7.1 2020/10/16 21976-00019 Date of first issue: 2014/10/15

Relative density : No data available

Density : No data available

Relative vapour density : Not applicable

Explosive properties : Not explosive

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

Particle characteristics

Particle size : No data available

10. STABILITY AND REACTIVITY

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

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.

Incompatible materials

Hazardous decomposition

products

Oxidizing agents

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:

Propylene glycol:

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

Acute inhalation toxicity : LC50 (Rabbit): > 159 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist

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

Assessment: The substance or mixture has no acute dermal

toxicity

Titanium dioxide:

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



Desogestrel Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 2020/03/23

 7.1
 2020/10/16
 21976-00019
 Date of first issue: 2014/10/15

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:

Propylene glycol:

Species : Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation

Titanium dioxide:

Species : Rabbit

Result : No skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Propylene glycol:

Species : Rabbit

Result : No eye irritation

Method : OECD Test Guideline 405

Titanium dioxide:

Species : Rabbit

Result : No eye irritation

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:

Propylene glycol:

Test Type : Maximisation Test



Desogestrel Formulation



Version Revision Date: SDS Number: Date of last issue: 2020/03/23 7.1 2020/10/16 21976-00019 Date of first issue: 2014/10/15

Exposure routes : Skin contact
Species : Guinea pig
Result : negative

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:

Propylene glycol:

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

Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo

cytogenetic assay) Species: Mouse

Application Route: Intraperitoneal injection

Result: negative

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:

Propylene glycol:

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

Desogestrel Formulation



Version Revision Date: SDS Number: Date of last issue: 2020/03/23 7.1 2020/10/16 21976-00019 Date of first issue: 2014/10/15

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-

ment

Limited evidence of carcinogenicity in inhalation studies with

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:

Propylene glycol:

Effects on fertility : Test Type: Three-generation reproduction toxicity study

Species: Mouse

Application Route: Ingestion

Result: negative

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Mouse

Application Route: Ingestion

Result: negative

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 developer: Test Type: Embryo-foetal development





Version Revision Date: SDS Number: Date of last issue: 2020/03/23 7.1 2020/10/16 21976-00019 Date of first issue: 2014/10/15

ment 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.

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:

Propylene glycol:

Species : Rat, male
NOAEL : 1,700 mg/kg
Application Route : Ingestion
Exposure time : 2 yr

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 Formulation



Version Revision Date: SDS Number: Date of last issue: 2020/03/23 7.1 2020/10/16 21976-00019 Date of first issue: 2014/10/15

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,

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:

Propylene glycol:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 40,613 mg/l

Exposure time: 96 h

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Ceriodaphnia dubia (water flea)): 18,340 mg/l

Exposure time: 48 h

Toxicity to algae/aquatic

plants

ErC50 (Skeletonema costatum (marine diatom)): 19,300 mg/l

Exposure time: 72 h

Desogestrel Formulation



Version **Revision Date:** SDS Number: Date of last issue: 2020/03/23 2020/10/16 21976-00019 Date of first issue: 2014/10/15 7.1

Method: OECD Test Guideline 201

Toxicity to daphnia and other :

aquatic invertebrates (Chron-

ic toxicity)

Toxicity to microorganisms

NOEC (Ceriodaphnia dubia (water flea)): 13,020 mg/l

Exposure time: 7 d

NOEC (Pseudomonas putida): > 20,000 mg/l

Exposure time: 18 h

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

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





 Version
 Revision Date:
 SDS Number:
 Date of last issue: 2020/03/23

 7.1
 2020/10/16
 21976-00019
 Date of first issue: 2014/10/15

M-Factor (Chronic aquatic

toxicity)

Toxicity to microorganisms

10,000

EC50: > 1,000 mg/l

Exposure time: 3 h
Test Type: Respiration inhibition

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:

Propylene glycol:

Biodegradability : Result: Readily biodegradable.

Biodegradation: 98.3 % Exposure time: 28 d

Method: OECD Test Guideline 301F

Desogestrel:

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

Remarks: Based on data from similar materials

Bioaccumulative potential

Components:

Propylene glycol:

Partition coefficient: n-

octanol/water

log Pow: -1.07

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 environ-

mental compartments

log Koc: 2.84

Hazardous to the ozone layer

Not applicable

Desogestrel Formulation



Version **Revision Date:** SDS Number: Date of last issue: 2020/03/23 2020/10/16 21976-00019 Date of first issue: 2014/10/15 7.1

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.

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/ID No. UN 3077

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

(Desogestrel)

Class 9 Packing group Ш

Miscellaneous Labels

Packing instruction (cargo

aircraft)

Packing instruction (passen-

ger aircraft)

Environmentally hazardous yes

IMDG-Code

UN number UN 3077

Proper shipping name ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

956

956

(Desogestrel)

Class 9 Packing group Ш Labels 9

F-A, S-F EmS Code Marine pollutant yes

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

Not applicable for product as supplied.

National Regulations

Refer to section 15 for specific national regulation.



Desogestrel Formulation

☆ ORGANON

Version Revision Date: SDS Number: Date of last issue: 2020/03/23 7.1 2020/10/16 21976-00019 Date of first issue: 2014/10/15

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

Related Regulations

Fire Service Law

Not applicable to dangerous materials / designated flammables.

Chemical Substance Control Law

Priority Assessment Chemical Substance

Chemical name	Number
Propane-1,2-diol	106

Industrial Safety and Health Law

Harmful Substances Prohibited from Manufacture

Not applicable

Harmful Substances Required Permission for Manufacture

Not applicable

Substances Prevented From Impairment of Health

Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity

Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity

Not applicable

Substances Subject to be Notified Names

Article 57-2 (Enforcement Order Table 9)

die er 2 (Emereement erder rasie e)				
Chemical name	Number	Concentration (%)		
Titanium(IV) oxide	191	>=0.1 - <1		

Substances Subject to be Indicated Names

Not applicable

Ordinance on Prevention of Hazards Due to Specified Chemical Substances

Not applicable

Ordinance on Prevention of Lead Poisoning

Not applicable

Ordinance on Prevention of Tetraalkyl Lead Poisoning

Not applicable

Ordinance on Prevention of Organic Solvent Poisoning

Not applicable

Desogestrel Formulation



Version Revision Date: SDS Number: Date of last issue: 2020/03/23 7.1 2020/10/16 21976-00019 Date of first issue: 2014/10/15

Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)

Not applicable

Poisonous and Deleterious Substances Control Law

Not applicable

Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof

Not applicable

High Pressure Gas Safety Act

Not applicable

Explosive Control Law

Not applicable

Vessel Safety Law

Miscellaneous dangerous substances and articles (Article 2 and 3 of rules on shipping and storage of dangerous goods and its Attached Table 1)

Aviation Law

Miscellaneous dangerous substances and articles (Article 194 of The Enforcement Rules of Aviation Law and its Attached Table 1)

Marine Pollution and Sea Disaster Prevention etc Law

Bulk transportation : Not classified as noxious liquid substance

Pack transportation : Classified as marine pollutant

Narcotics and Psychotropics Control Act

Narcotic or Psychotropic Raw Material (Export / Import Permission)

Not applicable

Specific Narcotic or Psychotropic Raw Material (Export / Import permission)

Not applicable

Waste Disposal and Public Cleansing Law

Industrial waste

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

Desogestrel Formulation



Version Revision Date: SDS Number: Date of last issue: 2020/03/23 7.1 2020/10/16 21976-00019 Date of first issue: 2014/10/15

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

JP OEL JSOH : Japan Society for Occupational Health. Recom-

mendation of Occupational Exposure Limits

ACGIH / TWA : 8-hour, time-weighted average
JP OEL JSOH / OEL-M : Occupational Exposure Limit-Mean

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; 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.

JP / EN