SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Public

ORGANON

Desogestrel / Ethinyl Estradiol Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 16.10.2020
2.5	09.04.2021	19059-00019	Date of first issue: 06.10.2014

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

1.1 Product identifier

Trade name : Desogestrel / Ethinyl Estradiol Formulation

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

Use of the Substance/Mixture : Pharmaceutical

1.3 Details of the supplier of the safety data sheet

Company : Organon & Co.
Shotton Lane
NE23 3JU Cramlington NU - Great Britain

Telephone : 44 1 670 59 30 00

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)

Carcinogenicity, Category 1A	H350: May cause cancer.
Reproductive toxicity, Category 1B	H360FD: May damage fertility. May damage the unborn child.
Specific target organ toxicity - repeated exposure, Category 1	H372: Causes damage to organs through prolonged or repeated exposure.
Long-term (chronic) aquatic hazard, Category 1	H410: Very toxic to aquatic life with long lasting effects.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :

Signal word : Danger

Hazard statements : H350 May cause cancer.
H360FD May damage fertility. May damage the unborn child.
H372 Causes damage to organs through prolonged or repeated exposure.

H410 Very toxic to aquatic life with long lasting effects.

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 protection/ 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
Ethinylestradiol

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. Registration number	Classification	Concentration (% w/w)
Desogestrel	54024-22-5 258-929-4	Repr. 1B; H360Fd STOT RE 1; H372 (Pituitary gland, Uterus (including cervix), Ovary, Mammary gland, Prostate) Aquatic Chronic 1; H410 M-Factor (Chronic aquatic toxicity): 10,000	>= 0.1 - < 0.25
Ethinylestradiol	57-63-6 200-342-2	Acute Tox. 4; H302 Carc. 1A; H350 Repr. 1B; H360FD STOT RE 1; H372 (Liver, Blood)	>= 0.025 - < 0.1

		Aquatic Chronic 1; H410 M-Factor (Chronic aquatic toxicity): 100,000	

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 advice 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 cause cancer.
May damage fertility. May damage 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.

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 products : 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 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.

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 protective equipment recommendations (see section 8).

6.2 Environmental precautions

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.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Sweep up or vacuum up spillage and collect in suitable container for disposal.
Avoid dispersal of dust in the air (i.e., clearing dust surfaces

with compressed air).
Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.
Local or national regulations may apply to releases and 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.

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 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.
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.

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.

Advice on common storage : Do not store with the following product types:
Strong oxidizing agents
Organic peroxides
Explosives
Gases

7.3 Specific end use(s)

Specific use(s) : No data available

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	9005-25-8	TWA (inhalable dust)	10 mg/m3	GB EH40
	Further information: For the purposes of these limits, respirable dust and inhalable dust are those fractions of airborne dust which will be collected when sampling is undertaken in accordance with the methods described in MDHS14/4 General methods for sampling and gravimetric analysis or respirable, thoracic and inhalable aerosols., The COSHH definition of a substance hazardous to health includes dust of any kind when present at a concentration in air equal to or greater than 10 mg.m-3 8-hour TWA of inhalable dust or 4 mg.m-3 8-hour TWA of respirable dust. This means that any dust will be subject to COSHH if people are exposed to dust above these levels. Some dusts have been assigned specific WELs and exposure to these must comply with the appropriate limits., Most industrial dusts contain particles of a wide range of sizes. The behaviour, deposition and fate of any particular particle after entry into the human respiratory system, and the body response that it elicits, depend on the nature and size of the particle. HSE distinguishes two size fractions for limit-setting purposes termed 'inhalable' and 'respirable'., Inhalable dust approximates to the fraction of airborne material that enters the nose and mouth during breathing and is therefore available for deposition in the respiratory tract. Respirable dust approximates to the fraction that penetrates to the gas exchange region of the lung. Fuller definitions and explanatory material are given in MDHS14/4., Where dusts contain components that have their own assigned WEL, all the relevant limits should be complied with., Where no specific short-term exposure limit is listed, a figure three times the long-term exposure limit should be used.			
		TWA (Respirable dust)	4 mg/m3	GB EH40
	Further information: For the purposes of these limits, respirable dust and inhalable dust are those fractions of airborne dust which will be collected when sampling is undertaken in accordance with the methods described in MDHS14/4 General methods for sampling and gravimetric analysis or respirable, thoracic and inhalable aerosols., The COSHH definition of a substance hazardous to health includes dust of any kind when present at a concentration in air equal to or greater than 10 mg.m-3 8-hour TWA of inhalable dust or 4			

	mg.m-3 8-hour TWA of respirable dust. This means that any dust will be subject to COSHH if people are exposed to dust above these levels. Some dusts have been assigned specific WELs and exposure to these must comply with the appropriate limits., Most industrial dusts contain particles of a wide range of sizes. The behaviour, deposition and fate of any particular particle after entry into the human respiratory system, and the body response that it elicits, depend on the nature and size of the particle. HSE distinguishes two size fractions for limit-setting purposes termed 'inhalable' and 'respirable'., Inhalable dust approximates to the fraction of airborne material that enters the nose and mouth during breathing and is therefore available for deposition in the respiratory tract. Respirable dust approximates to the fraction that penetrates to the gas exchange region of the lung. Fuller definitions and explanatory material are given in MDHS14/4., Where dusts contain components that have their own assigned WEL, all the relevant limits should be complied with., Where no specific short-term exposure limit is listed, a figure three times the long-term exposure limit should be used.			
Desogestrel	54024-22-5	TWA	0.04 µg/m3 (OEB 5)	Internal
		Wipe limit	0.4 µg/100 cm²	Internal
Ethinylestradiol	57-63-6	TWA	0.01 µg/m3 (OEB 5)	Internal
		Wipe limit	0.1 µg/100 cm²	Internal

Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:

Substance name	End Use	Exposure routes	Potential health effects	Value
Stearic acid	Workers	Inhalation	Long-term systemic effects	17.63 mg/m3
	Workers	Skin contact	Long-term systemic effects	10 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	4.348 mg/m3
	Consumers	Skin contact	Long-term systemic effects	5 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	2.5 mg/kg bw/day

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, disposable 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 exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Equipment should conform to BS EN 143
Filter type	:	Particulates type (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance	:	powder
Colour	:	White to light yellow
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, 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	:	1 g/cm³
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.

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, handling 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 exposure	:	Inhalation 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

Ethinylestradiol:

Acute oral toxicity	:	LD50 (Rat): 1,200 mg/kg
		LD50 (Mouse): 1,737 mg/kg
Acute inhalation toxicity	:	Remarks: No data available
Acute dermal toxicity	:	Remarks: No data available

Skin corrosion/irritation
Not classified based on available information.

Components:

Ethinylestradiol:

Remarks	:	No data available

Serious eye damage/eye irritation
Not classified based on available information.

Components:

Ethinylestradiol:

Remarks	:	No data available

Respiratory or skin sensitisation

Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.

Components:

Ethinylestradiol:

Remarks	:	No data available

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

Ethinylestradiol:

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

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

Test Type: Chromosome aberration test in vitro
Test system: Human lymphocytes
Result: equivocal

Genotoxicity in vivo : Test Type: Chromosomal aberration
Species: Mouse
Cell type: Bone marrow
Application Route: Oral
Result: positive

Test Type: Micronucleus test
Species: Mouse
Cell type: Bone marrow
Application Route: Oral
Result: negative

Germ cell mutagenicity- Assessment : Weight of evidence does not support classification as a germ cell mutagen.

Carcinogenicity

May cause cancer.

Components:

Desogestrel:

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

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

Result	:	negative

Ethinylestradiol:

Species	:	Rat, male and female
Application Route	:	Oral
Exposure time	:	2 Years
Result	:	negative
Species	:	Monkey, female
Application Route	:	Oral
Exposure time	:	10 Years
Result	:	negative
Carcinogenicity - Assessment	:	Positive evidence from human epidemiological studies

Reproductive toxicity

May damage fertility. May damage 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.

Ethinylestradiol:

Effects on fertility	:	Species: Hamster Fertility: LOAEL: 6.3 mg/kg body weight

Result: Effects on fertility

Effects on foetal development : Test Type: Four-generation reproduction toxicity study
Species: Rat
Application Route: Oral
Developmental Toxicity: LOAEL: > 0.006 mg/kg body weight
Result: Specific developmental abnormalities

Test Type: Two-generation reproduction toxicity study
Species: Rat, male and female
Application Route: Oral
Developmental Toxicity: LOAEL: 0.005 mg/kg body weight
Result: Specific developmental abnormalities

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

Ethinylestradiol:

Target Organs : Liver, Blood
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
Exposure time	:	52 Weeks
Target Organs	:	Pituitary gland, Uterus (including cervix), Ovary, Mammary gland, Prostate

Ethinylestradiol:

Species	:	Rat
NOAEL	:	0.25 mg/kg
LOAEL	:	0.5 mg/kg
Application Route	:	Oral
Exposure time	:	2 Weeks
Target Organs	:	Liver
Species	:	Rabbit
LOAEL	:	0.015 mg/kg
Application Route	:	Oral
Exposure time	:	20 Weeks
Target Organs	:	Liver
Species	:	Dog
NOAEL	:	0.04 mg/kg
LOAEL	:	0.2 mg/kg
Application Route	:	Oral
Exposure time	:	95 d
Target Organs	:	Blood
Species	:	Rat, male and female
NOAEL	:	0.0015 mg/kg
LOAEL	:	0.005 mg/kg
Application Route	:	Oral
Exposure time	:	2 yr
Target Organs	:	Reproductive organs, Mammary gland, Liver, Uterus (including cervix)

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

Ethinylestradiol:

Ingestion	:	Symptoms: Abdominal pain, Nausea, Vomiting, Diarrhoea, Headache, Dizziness, mood swings, Oedema, liver function change, water retention, hair loss, gynecomastia, effects on menstruation

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
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 (Chron-	:	NOEC: 1.2 mg/l Exposure time: 21 d

ic toxicity)		Species: Daphnia magna (Water flea) Remarks: Based on data from similar materials
M-Factor (Chronic aquatic toxicity)	:	10,000

Ethinylestradiol:

Toxicity to fish	:	LC50 (Lepomis macrochirus (Bluegill sunfish)): 1.6 mg/l Exposure time: 96 h Method: OECD Test Guideline 203
Toxicity to algae/aquatic plants	:	EC50 (Pseudokirchneriella subcapitata (green algae)): > 6.7 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 NOEC (Pseudokirchneriella subcapitata (green algae)): 6.7 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
Toxicity to microorganisms	:	EC50 : > 1,000 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209 NOEC : 24.9 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209
Toxicity to fish (Chronic toxicity)	:	NOEC: 0.01 µg/l Exposure time: 35 d Species: Pimephales promelas (fathead minnow) Method: OECD Test Guideline 210 NOEC: 0.00031 µg/l Exposure time: 339 d Species: Zebrafish
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC: 0.75 mg/l Exposure time: 21 d Species: Daphnia magna (Water flea) Method: OECD Test Guideline 211
M-Factor (Chronic aquatic toxicity)	:	100,000

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

Ethinylestradiol:

Bioaccumulation	:	Species: Lepomis macrochirus (Bluegill sunfish) Bioconcentration factor (BCF): 264 Method: OECD Test Guideline 305
Partition coefficient: n-octanol/water	:	log Pow: 4.15

12.4 Mobility in soil

Components:

Desogestrel:

Distribution among environmental compartments	:	log Koc: 2.84

Ethinylestradiol:

Distribution among environmental compartments	:	log Koc: 3.86

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.

12.6 Other adverse effects

Product:

Endocrine disrupting potential	:	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.

Contaminated packaging	:	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. Empty containers should be taken to an approved waste handling 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. (Ethinylestradiol, Desogestrel)
ADR	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Ethinylestradiol, Desogestrel)
RID	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Ethinylestradiol, Desogestrel)
IMDG	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Ethinylestradiol, Desogestrel)
IATA	:	Environmentally hazardous substance, solid, n.o.s. (Ethinylestradiol, Desogestrel)

14.3 Transport hazard class(es)

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 aircraft)	:	956
Packing instruction (LQ)	:	Y956
Packing group	:	III
Labels	:	Miscellaneous

IATA (Passenger)

Packing instruction (passenger aircraft)	:	956
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

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII) : Not applicable

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59). : Not applicable

REACH - List of substances subject to authorisation (Annex XIV) : Not applicable

Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable

Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable

Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Not applicable

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	Quantity 2
E1	ENVIRONMENTAL HAZARDS	100 t	200 t

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

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

H302 : Harmful if swallowed.
H350 : May cause cancer.
H360Fd : May damage fertility. Suspected of damaging the unborn

		child.
H360FD	:	May damage fertility. May damage 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

Acute Tox.	:	Acute toxicity
Aquatic Chronic	:	Long-term (chronic) aquatic hazard
Carc.	:	Carcinogenicity
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)

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 - 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 Agency, http://echa.europa.eu/

Classification of the mixture: **Classification procedure:**

Carc. 1A	H350	Calculation method
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.

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