SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758

Public

ORGANON

Nomegestrol / Estradiol Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 26.09.2023
5.0	06.04.2024	9371304-00007	Date of first issue: 27.08.2021

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

1.1 Product identifier

Trade name : Nomegestrol / Estradiol Formulation

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

Use of the Substance/Mixture : Pharmaceutical

Recommended restrictions on use : Not applicable

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 32 05

E-mail address of person responsible for the SDS : EHSSTEWARD@organon.com

1.4 Emergency telephone number

+1-215-631-6999

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)

Carcinogenicity, Category 1A	H350: May cause cancer.
Reproductive toxicity, Category 1A	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) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)

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:
Estradiol
17-Hydroxy-6-methyl-19-norpregna-4,6-diene-3,20-dione 17-acetate

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)
Estradiol	50-28-2 200-023-8	Carc. 1A; H350 Repr. 1A; H360FD STOT RE 1; H372 (Liver, Bone, Blood, Endocrine system)	>= 2.5 - < 10

		Aquatic Chronic 1; H410 ——————— M-Factor (Chronic aquatic toxicity): 1,000 ——————— specific concentration limit Carc. 1A; H350 >= 0.01 % Repr. 1A; H360FD >= 0.01 % STOT RE 1; H372 >= 0.01 % Carc. 1A; H350 >= 0.01 % Repr. 1A; H360FD >= 0.01 % STOT RE 1; H372 >= 0.01 %	
17-Hydroxy-6-methyl-19-norpregna-4,6-diene-3,20-dione 17-acetate	58652-20-3 261-379-8	Repr. 1A; H360F Aquatic Chronic 1; H410 ——————— M-Factor (Chronic aquatic toxicity): 10	>= 1 - < 2.5
Substances with a workplace exposure limit :			
Cellulose	9004-34-6 232-674-9		>= 10 - < 20
Talc	14807-96-6 238-877-9		>= 1 - < 10

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. If spillage enters rivers or watercourses, inform the Environment Agency (emergency telephone number 0800 807060).

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.

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 Self-reactive substances and mixtures 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

dust of any kind	10 mg/m3 Value type (Form of exposure): TWA (Inhalable) Basis: GB EH40
	4 mg/m3 Value type (Form of exposure): TWA (Respirable fraction) Basis: GB EH40

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Cellulose	9004-34-6	TWA (inhalable dust)	10 mg/m3	GB EH40
		TWA (Respirable dust)	4 mg/m3	GB EH40
		STEL (inhalable dust)	20 mg/m3	GB EH40
Estradiol	50-28-2	TWA	0.05 µg/m3 (OEB 5)	Internal
	Further information: Skin			
		Wipe limit	0.5 µg/100 cm²	Internal
17-Hydroxy-6-methyl-19-norpregna-4,6-diene-3,20-dione 17-acetate	58652-20-3	TWA	0.2 µg/m3	Internal
		Wipe limit	2 µg/100 cm²	Internal
Talc	14807-96-6	TWA (Respirable dust)	1 mg/m3	GB EH40

8.2 Exposure controls

Engineering measures

Minimize workplace exposure concentrations.
Apply measures to prevent dust explosions.
Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment).
If sufficient ventilation is unavailable, use with local exhaust ventilation.

Personal protective equipment

Eye/face protection : Wear the following personal protective equipment:
Safety goggles
Equipment should conform to BS EN 166

Hand protection

Material : Chemical-resistant gloves

Remarks : Choose gloves to protect hands against chemicals depending on the concentration and quantity of the hazardous substance and specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Wash hands before breaks and at the end of workday.

Skin and body protection : Select appropriate protective clothing based on chemical resistance data and an assessment of the local exposure potential.
Skin contact must be avoided by using impervious protective clothing (gloves, aprons, boots, etc).

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
Odour	:	odourless
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	:	No data available
Evaporation rate	:	No data available
Flammability (solid, gas)	:	May form explosive dust-air mixture during processing, handling or other means.
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapour pressure	:	No data available
Relative vapour density	:	No data available
Relative density	:	No data available
Density	:	1 g/cm³
Solubility(ies)		
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, dynamic	:	No data available

Viscosity, kinematic	:	No data available
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.

9.2 Other information

Flammability (liquids)	:	No data available
Molecular weight	:	No data available
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:

Estradiol:

Acute oral toxicity	:	LD50 (Rat): > 2,000 mg/kg
Acute toxicity (other routes of administration)	:	LD50 (Rat): > 300 mg/kg Application Route: Subcutaneous

17-Hydroxy-6-methyl-19-norpregna-4,6-diene-3,20-dione 17-acetate:

Acute oral toxicity	:	LD50 (Rat): > 2,000 mg/kg LD50 (Mouse): > 2,000 mg/kg
Acute toxicity (other routes of administration)	:	LD50 (Rat): > 2,000 mg/kg Application Route: Intraperitoneal

Cellulose:

Acute oral toxicity	:	LD50 (Rat): > 5,000 mg/kg
Acute inhalation toxicity	:	LC50 (Rat): > 5.8 mg/l Exposure time: 4 h Test atmosphere: dust/mist
Acute dermal toxicity	:	LD50 (Rabbit): > 2,000 mg/kg

Talc:

Acute oral toxicity	:	LD50 (Rat): > 5,000 mg/kg Remarks: Based on data from similar materials

Skin corrosion/irritation

Not classified based on available information.

Components:

Talc:

Species	:	Rabbit
Result	:	No skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Estradiol:

Result	:	No eye irritation

Talc:

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:

Estradiol:

Exposure routes	:	Skin contact
Species	:	Guinea pig
Assessment	:	Does not cause skin sensitisation.
Result	:	negative

Talc:

Exposure routes	:	Skin contact
Species	:	Humans
Result	:	negative

Germ cell mutagenicity

Not classified based on available information.

Components:

Estradiol:

Genotoxicity in vitro	:	Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro) Test system: mammalian cells Result: positive Test Type: Chromosome aberration test in vitro Test system: mammalian cells Result: positive Test Type: Chromosomal aberration Test system: mammalian cells Result: positive
Genotoxicity in vivo	:	Test Type: Chromosomal aberration Species: Rat Cell type: Bone marrow Result: negative Test Type: Chromosomal aberration Species: Mouse Cell type: Bone marrow Result: negative

17-Hydroxy-6-methyl-19-norpregna-4,6-diene-3,20-dione 17-acetate:

Genotoxicity in vitro	:	Test Type: Ames test Result: negative Test Type: Chromosome aberration test in vitro Result: negative Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro) Result: negative Test Type: In vitro mammalian cell gene mutation test Result: negative
Genotoxicity in vivo	:	Test Type: In vivo micronucleus test Species: Rat Application Route: Oral Result: negative Test Type: In vivo micronucleus test Species: Mouse Application Route: Oral Result: negative

Cellulose:

Genotoxicity in vitro	:	Test Type: Bacterial reverse mutation assay (AMES) Result: negative Test Type: In vitro mammalian cell gene mutation test Result: negative
Genotoxicity in vivo	:	Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Mouse Application Route: Ingestion Result: negative

Talc:

Genotoxicity in vitro	:	Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro) Result: negative
Genotoxicity in vivo	:	Test Type: Chromosome aberration test in vitro Species: Rat Application Route: Ingestion Result: negative

Carcinogenicity

May cause cancer.

Components:

Estradiol:

Species	:	Mouse
Application Route	:	Ingestion
Exposure time	:	24 Months
LOAEL	:	100 µg/kg
Result	:	positive
Target Organs	:	female reproductive organs

Species	:	Rat
Application Route	:	Subcutaneous
Exposure time	:	13 weeks
LOAEL	:	20 mg/kg body weight
Result	:	positive
Target Organs	:	Endocrine system

Carcinogenicity - Assessment	:	Positive evidence from human epidemiological studies

17-Hydroxy-6-methyl-19-norpregna-4,6-diene-3,20-dione 17-acetate:

Species	:	Rat
Application Route	:	oral (feed)
Activity duration	:	52 Weeks
	:	10 mg/kg body weight
Result	:	negative

Species	:	Mouse
Application Route	:	oral (feed)
	:	20 mg/kg body weight
Result	:	positive
Target Organs	:	Mammary gland, Pituitary gland

Carcinogenicity - Assessment	:	Weight of evidence does not support classification as a carcinogen

Cellulose:

Species	:	Rat
Application Route	:	Ingestion
Exposure time	:	72 weeks
Result	:	negative

Talc:

Species	:	Mouse
Application Route	:	inhalation (dust/mist/fume)
Exposure time	:	2 Years
Result	:	negative

Reproductive toxicity

May damage fertility. May damage the unborn child.

Components:

Estradiol:

Effects on fertility	:	Test Type: One-generation reproduction toxicity study Species: Rat Application Route: Ingestion Fertility: LOAEL: 0.5 mg/kg body weight Result: Effects on fertility Test Type: One-generation reproduction toxicity study Species: Rat Duration of Single Treatment: 90 d Fertility: LOAEL: 0.69 mg/kg body weight Result: Effects on fertility Test Type: Two-generation study Species: Mouse Application Route: Oral Fertility: LOAEL: 0.1 mg/kg body weight Result: Effects on fertility
Effects on foetal development	:	Test Type: Embryo-foetal development Species: Mouse, female Application Route: Subcutaneous Teratogenicity: LOAEL: 4 mg/kg body weight Symptoms: Malformations were observed. Result: positive, Teratogenic effects Test Type: One-generation reproduction toxicity study Species: Rat Application Route: Subcutaneous Teratogenicity: LOAEL: 2.5 µg/kg body weight Symptoms: Reduced body weight Result: positive, Embryotoxic effects and adverse effects on the offspring were detected. Test Type: Embryo-foetal development Species: Rat Application Route: Subcutaneous Developmental Toxicity: LOAEL: 0.2 mg/kg body weight Symptoms: Early Resorptions / resorption rate, Reduced number of viable fetuses, Reduced body weight Result: Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses
Reproductive toxicity - Assessment	:	May damage fertility. May damage the unborn child.

17-Hydroxy-6-methyl-19-norpregna-4,6-diene-3,20-dione 17-acetate:

Effects on foetal development	:	Test Type: Development Species: Rat Application Route: Oral Result: negative

		Test Type: Embryo-foetal development Species: Rabbit Application Route: Oral Result: negative, No teratogenic effects
Reproductive toxicity - Assessment	:	Positive evidence of adverse effects on sexual function and fertility from human epidemiological studies.

Cellulose:

Effects on fertility	:	Test Type: One-generation reproduction toxicity study Species: Rat Application Route: Ingestion Result: negative
Effects on foetal development	:	Test Type: Fertility/early embryonic development Species: Rat Application Route: Ingestion Result: negative

Talc:

Effects on foetal development	:	Test Type: Embryo-foetal development Species: Rat Application Route: Ingestion Result: negative

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Causes damage to organs through prolonged or repeated exposure.

Components:

Estradiol:

Target Organs	:	Liver, Bone, Blood, Endocrine system
Assessment	:	Causes damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

Estradiol:

Species	:	Rat
LOAEL	:	>= 0.17 mg/kg
Application Route	:	Ingestion
Exposure time	:	90 d
Target Organs	:	Mammary gland, Ovary, Uterus (including cervix), Liver, Bone, Endocrine system, Blood, Testis

17-Hydroxy-6-methyl-19-norpregna-4,6-diene-3,20-dione 17-acetate:

Species	:	Mouse
NOAEL	:	20 mg/kg
Application Route	:	Oral
Exposure time	:	52 Weeks

Species	:	Rat
NOAEL	:	20 mg/kg
Application Route	:	Oral
Exposure time	:	52 Weeks

Cellulose:

Species	:	Rat
NOAEL	:	>= 9,000 mg/kg
Application Route	:	Ingestion
Exposure time	:	90 Days

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

Estradiol:

Inhalation	:	Symptoms: tingling, Nose bleeding
Skin contact	:	Symptoms: Skin irritation, Redness, pruritis
Ingestion	:	Symptoms: Headache, Gastrointestinal disturbance, Dizziness, Vomiting, Diarrhoea, water retention, liver function change, changes in libido, breast tenderness, menstrual irregularities

17-Hydroxy-6-methyl-19-norpregna-4,6-diene-3,20-dione 17-acetate:

Ingestion	:	Symptoms: acne, amenorrhea, Headache, Dizziness, Nausea, breast tenderness, changes in libido, insomnia, musculoskeletal pain, mood swings, muscle pain, muscle twitching

SECTION 12: Ecological information

12.1 Toxicity

Components:

Estradiol:

Toxicity to fish	:	LC50 (Oryzias latipes (Japanese medaka)): 3.9 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 2.7 mg/l Exposure time: 48 h
Toxicity to algae/aquatic plants	:	NOEC (Pseudokirchneriella subcapitata (green algae)): 1.7 mg/l

		Exposure time: 72 h Method: OECD Test Guideline 201 EC50 (Pseudokirchneriella subcapitata (green algae)): > 1.7 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
Toxicity to microorganisms	:	EC50 : > 100 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209 NOEC : 100 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209
Toxicity to fish (Chronic toxicity)	:	NOEC: 0.000003 mg/l Exposure time: 160 d Species: Oryzias latipes (Japanese medaka) Method: OECD Test Guideline 210
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC: 0.2 mg/l Exposure time: 21 d Species: Daphnia magna (Water flea)
M-Factor (Chronic aquatic toxicity)	:	1,000

17-Hydroxy-6-methyl-19-norpregna-4,6-diene-3,20-dione 17-acetate:

Toxicity to algae/aquatic plants	:	EC50 (Pseudokirchneriella subcapitata (green algae)): > 3.07 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 NOEC (Pseudokirchneriella subcapitata (green algae)): 0.69 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
Toxicity to microorganisms	:	EC50 (Natural microorganism): > 2.8 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209 NOEC (Natural microorganism): 2.8 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209 Remarks: No toxicity at the limit of solubility
Toxicity to fish (Chronic tox-	:	NOEC: 0.0013 mg/l

icity)		Exposure time: 27 d Species: Zebrafish
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC: 3.65 mg/l Exposure time: 21 d Species: Daphnia magna (Water flea) Method: OECD Test Guideline 211 Remarks: No toxicity at the limit of solubility
M-Factor (Chronic aquatic toxicity)	:	10

Cellulose:

Toxicity to fish	:	LC50 (Oryzias latipes (Japanese medaka)): > 100 mg/l Exposure time: 48 h Remarks: Based on data from similar materials

Talc:

Toxicity to fish	:	LC50 (Brachydanio rerio (zebrafish)): > 100,000 mg/l Exposure time: 24 h

12.2 Persistence and degradability

Components:

Estradiol:

Biodegradability	:	Result: rapidly degradable Biodegradation: 84 % Exposure time: 24 hrs

Cellulose:

Biodegradability	:	Result: Readily biodegradable.

12.3 Bioaccumulative potential

Components:

Estradiol:

Partition coefficient: n-octanol/water	:	log Pow: 4.01

17-Hydroxy-6-methyl-19-norpregna-4,6-diene-3,20-dione 17-acetate:

Bioaccumulation	:	Species: Zebrafish Bioconcentration factor (BCF): 44
Partition coefficient: n-octanol/water	:	log Pow: 3.7

12.4 Mobility in soil

Components:

Estradiol:

Distribution among environmental compartments	:	log Koc: 3.81

17-Hydroxy-6-methyl-19-norpregna-4,6-diene-3,20-dione 17-acetate:

Distribution among environmental compartments	:	log Koc: 3.35 Method: OECD Test Guideline 106

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	:	This substance/mixture does not contain components considered to have endocrine disrupting properties for environment according to UK REACH Article 57(f).

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. Do not dispose of waste into sewer.
Contaminated packaging	:	Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

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.
(Estradiol, 17-Hydroxy-6-methyl-19-norpregna-4,6-diene-3,20-dione 17-acetate)

ADR : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
(Estradiol, 17-Hydroxy-6-methyl-19-norpregna-4,6-diene-3,20-dione 17-acetate)

RID : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
(Estradiol, 17-Hydroxy-6-methyl-19-norpregna-4,6-diene-3,20-dione 17-acetate)

IMDG : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
(Estradiol, 17-Hydroxy-6-methyl-19-norpregna-4,6-diene-3,20-dione 17-acetate)

IATA : Environmentally hazardous substance, solid, n.o.s.
(Estradiol, 17-Hydroxy-6-methyl-19-norpregna-4,6-diene-3,20-dione 17-acetate)

14.3 Transport hazard class(es)

	Class	Subsidiary risks
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

Relevant EU provisions transposed through retained EU law

UK REACH List of restrictions (Annex 17)	:	Not applicable
UK REACH Candidate list of substances of very high concern (SVHC) for Authorisation	:	Not applicable
The Persistent Organic Pollutants Regulations (retained Regulation (EU) 2019/1021 as amended for Great Britain)	:	Not applicable
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer	:	Not applicable
UK REACH List of substances subject to authorisation (Annex XIV)	:	Not applicable
GB Export and import of hazardous chemicals - Prior Informed Consent (PIC) Regulation	:	Not applicable

Control of Major Accident Hazards Regulations 2015 (COMAH)

		Quantity 1	Quantity 2
E1	ENVIRONMENTAL HAZARDS	100 t	200 t

Other regulations:

Take note of The Management of Health and Safety at Work Regulations 1999 (requirements relating to new and expectant mothers at work contained in Regulation 16 to 18) and of the Pregnant Workers Directive 92/85/EEC.
Take note of The Management of Health and Safety at Work Regulations 1999 (requirements relating to protection of young people at work contained in Regulation 19) and of Directive 94/33/EC on the protection of young people at work.

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

H350	:	May cause cancer.
H360F	:	May damage fertility.
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

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)
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 - 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; TECI - Thailand Existing Chemicals Inventory; 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

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. 1A	H360FD	Calculation method
STOT RE 1	H372	Calculation method
Aquatic Chronic 1	H410	Calculation method

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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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