

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

1.1. Product identifier

Product form : Mixture
Product name : Etonogestrel impurity mixture
Product code : 202300496

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

Relevant identified uses

Use of the substance/mixture : Scientific research and development
Technical testing and analysis
For professional use only
Function or use category : Laboratory chemicals

Uses advised against

Restrictions on use : Not for food, drug or home use

1.3. Details of the supplier of the safety data sheet

European Directorate for the Quality of Medicines & Healthcare
EDQM, Council of Europe
7, Allée Kastner, CS30026
F 67081 Strasbourg
France
T +33(0)388412035, F +33(0)388412771
sds@edqm.eu, www.edqm.eu

1.4. Emergency telephone number

Emergency number : +33(0)390215608

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Flammable liquids, Category 2	H225
Acute toxicity (oral), Category 4	H302
Acute toxicity (dermal), Category 4	H312
Acute toxicity (inhal.), Category 4	H332
Serious eye damage/eye irritation, Category 2	H319
Hazardous to the aquatic environment – Chronic Hazard, Category 1	H410

Full text of H- and EUH-statements: see section 16

Adverse physicochemical, human health and environmental effects

Harmful if swallowed. Harmful in contact with skin. Harmful if inhaled. Very toxic to aquatic life with long lasting effects. Causes serious eye irritation. Highly flammable liquid and vapour.

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP) :



GHS02

GHS07

GHS09

Signal word (CLP) :

Danger

Contains

Acetonitrile

Etonogestrel impurity mixture

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Hazard statements (CLP)	: H225 - Highly flammable liquid and vapour. H302+H312+H332 - Harmful if swallowed, in contact with skin or if inhaled. H319 - Causes serious eye irritation. H410 - Very toxic to aquatic life with long lasting effects.
Precautionary statements (CLP)	: P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P233 - Keep container tightly closed. P240 - Ground and bond container and receiving equipment. P241 - Use explosion-proof electrical/ventilating/lighting equipment. P261 - Avoid breathing dust/fume/gas/mist/vapours/spray. P264 - Wash hands, forearms and face thoroughly after handling. P270 - Do not eat, drink or smoke when using this product. P271 - Use only outdoors or in a well-ventilated area. P273 - Avoid release to the environment. P280 - Wear protective gloves/protective clothing/eye protection/face protection/hearing protection. P301+P312 - IF SWALLOWED: Call a POISON CENTRE or doctor if you feel unwell. P302+P352 - IF ON SKIN: Wash with plenty of water. P304+P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing. P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P312 - Call a POISON CENTRE or doctor if you feel unwell. P321 - Specific treatment (see supplemental first aid instruction on this label). P330 - Rinse mouth. P337+P313 - If eye irritation persists: Get medical advice/attention. P362+P364 - Take off contaminated clothing and wash it before reuse. P370+P378 - In case of fire: Use media other than water to extinguish. P391 - Collect spillage. P403+P235 - Store in a well-ventilated place. Keep cool. P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

Labelling according to: Exemption for inner packaging where the contents do not exceed 10ml.

Hazardous ingredients : Acetonitrile

2.3. Other hazards

Contains no PBT and/or vPvB substances $\geq 0.1\%$ assessed in accordance with REACH Annex XIII

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or substance(s) are not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %

Component	
Substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605	13-Ethyl-11-methylene-gon-4-ene-3,17-dione (54024-17-8) ⁽¹⁾ , 13-Ethyl-17-hydroxy-11-methylene-18,19-dinor-17 α -pregn-5-en-20-yn-3-one (3081732-55-7) ⁽¹⁾

⁽¹⁾ Substance(s) in concentration below 0.1 % and displayed on a voluntary basis

Other information : Warning - The product has not been fully tested.

Etonogestrel impurity mixture

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Acetonitrile	CAS-No.: 75-05-8 EC-No.: 200-835-2 EC Index-No.: 608-001-00-3	99 – 100	Flam. Liq. 2, H225 Acute Tox. 4 (Inhalation), H332 (ATE=11 mg/l/4h) Acute Tox. 4 (Dermal), H312 (ATE=1100 mg/kg bodyweight) Acute Tox. 4 (Oral), H302 (ATE=500 mg/kg bodyweight) Eye Irrit. 2, H319
13-Ethyl-11-methylene-gon-4-ene-3,17-dione	CAS-No.: 54024-17-8	< 0,1	ED ENV 1, EUH430 ED HH 1, EUH380 Carc. 2, H351 Repr. 1A, H360 STOT RE 1, H372 Aquatic Chronic 1, H410 (M=10000)
13-Ethyl-17-hydroxy-11-methylene-18,19-dinor-17 α -pregn-5-en-20-yn-3-one	CAS-No.: 3081732-55-7	< 0,1	ED ENV 1, EUH430 ED HH 1, EUH380 Carc. 2, H351 Repr. 1A, H360 STOT RE 1, H372 Aquatic Chronic 1, H410 (M=10000)

Full text of H- and EUH-statements: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general	: In all cases of doubt, or when symptoms persist, seek medical attention.
First-aid measures after inhalation	: Remove person to fresh air and keep comfortable for breathing. Allow the victim to rest. Immediately call a POISON CENTER/doctor.
First-aid measures after skin contact	: Take off contaminated clothing. Wash skin thoroughly with mild soap and water. Get immediate medical advice/attention.
First-aid measures after eye contact	: Rinse immediately and thoroughly, pulling the eyelids well away from the eye (15 minutes minimum). Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention if pain, blinking or redness persists.
First-aid measures after ingestion	: Rinse mouth out with water (only if the person is conscious). Never give anything by mouth to an unconscious person. Immediately call a POISON CENTER/doctor.

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

Symptoms/effects after eye contact	: Causes serious eye irritation. Redness, pain.
------------------------------------	---

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

No additional information available

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	: Use extinguishing media appropriate for surrounding fire. Carbon dioxide. Water spray. Dry powder. Extinguishing blanket.
Unsuitable extinguishing media	: Do not use a heavy water stream.

Etonogestrel impurity mixture

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire : Incomplete combustion releases dangerous carbon monoxide, carbon dioxide and other toxic gases. Toxic fumes may be released.

5.3. Advice for firefighters

Firefighting instructions : Prevent fire fighting water from entering the environment.
Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : Avoid contact with skin, eyes and clothing.

For non-emergency personnel

Emergency procedures : Evacuate unnecessary personnel.

For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

6.2. Environmental precautions

Avoid release to the environment. Prevent entry to sewers and public waters.

6.3. Methods and material for containment and cleaning up

For containment : Absorb with an inert material and place in an appropriate waste disposal container.
Methods for cleaning up : Clean contaminated surfaces with an excess of water. Clean with the help of detergents.

6.4. Reference to other sections

See Section 13 for disposal information.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Avoid all unnecessary exposure. Ensure good ventilation of the work station.
Hygiene measures : Do not eat, drink or smoke when using this product. Contaminated work clothing should not be allowed out of the workplace. Wash hands before work breaks and after finishing work.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in a well-ventilated place. Keep container tightly closed. Keep away from heat and direct sunlight.
Packaging materials : Keep in original containers.

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

Etonogestrel impurity mixture

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

8.2. Exposure controls

Appropriate engineering controls

Appropriate engineering controls:

Ensure good ventilation of the work station. Both local exhaust and general room ventilation are usually required. Material should be handled in a laboratory hood whenever possible.

Personal protection equipment

Eye and face protection

Eye protection:

Wear eye protection. Safety glasses with side shields. (EN 166)

Skin protection

Skin and body protection:

Wear suitable protective clothing. Laboratory use : Lab coat. (EN 13034)

Hand protection:

Wear suitable gloves. Chemically resistant protective gloves. (EN 374)

Respiratory protection

Respiratory protection:

In case of mist, spray or aerosol exposure: Breathing apparatus with filter (P3). Where excessive vapour may result, wear approved mask .

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Colour	: Not available
Odour	: Not available
Odour threshold	: Not available
Melting point	: Not available
Freezing point	: Not available
Boiling point	: Not available
Flammability	: Highly flammable liquid and vapour.
Lower explosion limit	: Not available
Upper explosion limit	: Not available
Flash point	: Not available
Auto-ignition temperature	: Not available
Decomposition temperature	: Not available
pH	: Not available
Viscosity, kinematic	: Not available
Solubility	: Not available
Partition coefficient n-octanol/water (Log Kow)	: Not available
Vapour pressure	: Not available
Vapour pressure at 50°C	: Not available
Density	: Not available
Relative density	: Not available
Relative vapour density at 20°C	: Not available
Particle characteristics	: Not applicable

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Highly flammable liquid and vapour.

Etonogestrel impurity mixture

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

10.2. Chemical stability

No additional information available

10.3. Possibility of hazardous reactions

No additional information available

10.4. Conditions to avoid

No additional information available

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

No additional information available

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral) : Harmful if swallowed.
Acute toxicity (dermal) : Harmful in contact with skin.
Acute toxicity (inhalation) : Harmful if inhaled.

Etonogestrel impurity mixture

ATE CLP (oral)	500,05 mg/kg bodyweight
ATE CLP (dermal)	1100,11 mg/kg bodyweight
ATE CLP (gases)	4500 ppmv/4h
ATE CLP (vapours)	11 mg/l/4h
ATE CLP (dust,mist)	1,5 mg/l/4h

13-Ethyl-11-methylene-gon-4-ene-3,17-dione (54024-17-8)

LD50 oral rat > 2000 mg/kg (estimated value)

13-Ethyl-17-hydroxy-11-methylene-18,19-dinor-17 α -pregn-5-en-20-yn-3-one (3081732-55-7)

LD50 oral rat > 2000 mg/kg (estimated value)

Skin corrosion/irritation : Not classified (Based on available data, the classification criteria are not met)

Acetonitrile (75-05-8)

pH 6,5 – 7,5 at 50g/l (20°C)

Serious eye damage/irritation : Causes serious eye irritation.

Acetonitrile (75-05-8)

pH 6,5 – 7,5 at 50g/l (20°C)

Respiratory or skin sensitisation : Not classified (Based on available data, the classification criteria are not met)
Germ cell mutagenicity : Not classified (Based on available data, the classification criteria are not met)
Carcinogenicity : Not classified (Based on available data, the classification criteria are not met)
Reproductive toxicity : Not classified (Based on available data, the classification criteria are not met)
STOT-single exposure : Not classified (Based on available data, the classification criteria are not met)
STOT-repeated exposure : Not classified (Based on available data, the classification criteria are not met)

13-Ethyl-11-methylene-gon-4-ene-3,17-dione (54024-17-8)

STOT-repeated exposure Causes damage to organs (cardiovascular system, endocrine system) through prolonged or repeated exposure.

Etonogestrel impurity mixture

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

13-Ethyl-17-hydroxy-11-methylene-18,19-dinor-17 α -pregn-5-en-20-yn-3-one (3081732-55-7)

STOT-repeated exposure	Causes damage to organs (cardiovascular system, endocrine system) through prolonged or repeated exposure.
------------------------	---

Aspiration hazard : Not classified (Based on available data, the classification criteria are not met)

11.2. Information on other hazards

Endocrine disrupting properties

Component

13-Ethyl-11-methylene-gon-4-ene-3,17-dione (54024-17-8)	Has an endocrine mode of action, i.e. it alters the function(s) of the endocrine system
13-Ethyl-17-hydroxy-11-methylene-18,19-dinor-17 α -pregn-5-en-20-yn-3-one (3081732-55-7)	Has an endocrine mode of action, i.e. it alters the function(s) of the endocrine system

SECTION 12: Ecological information

12.1. Toxicity

Hazardous to the aquatic environment, short-term (acute) : Not classified (Based on available data, the classification criteria are not met)

Hazardous to the aquatic environment, long-term (chronic) : Very toxic to aquatic life with long lasting effects.

13-Ethyl-11-methylene-gon-4-ene-3,17-dione (54024-17-8)

LC50 - Fish [1]	< 0,1 mg/l (estimated value)
-----------------	------------------------------

13-Ethyl-17-hydroxy-11-methylene-18,19-dinor-17 α -pregn-5-en-20-yn-3-one (3081732-55-7)

LC50 - Fish [1]	< 0,1 mg/l (estimated value)
-----------------	------------------------------

12.2. Persistence and degradability

Etonogestrel impurity mixture

Persistence and degradability	Not rapidly degradable
-------------------------------	------------------------

13-Ethyl-11-methylene-gon-4-ene-3,17-dione (54024-17-8)

Persistence and degradability	Not rapidly degradable
-------------------------------	------------------------

13-Ethyl-17-hydroxy-11-methylene-18,19-dinor-17 α -pregn-5-en-20-yn-3-one (3081732-55-7)

Persistence and degradability	Not rapidly degradable
-------------------------------	------------------------

Acetonitrile (75-05-8)

Persistence and degradability	Rapidly degradable
-------------------------------	--------------------

12.3. Bioaccumulative potential

Acetonitrile (75-05-8)

Partition coefficient n-octanol/water (Log Pow)	-0,34
---	-------

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

Etonogestrel impurity mixture

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

12.6. Endocrine disrupting properties

Component	
13-Ethyl-11-methylene-gon-4-ene-3,17-dione (54024-17-8)	Has an endocrine mode of action, i.e. it alters the function(s) of the endocrine system
13-Ethyl-17-hydroxy-11-methylene-18,19-dinor-17 α -pregn-5-en-20-yn-3-one (3081732-55-7)	Has an endocrine mode of action, i.e. it alters the function(s) of the endocrine system

12.7. Other adverse effects

No additional information available




SECTION 13: Disposal considerations

13.1. Waste treatment methods

No additional information available

SECTION 14: Transport information

In accordance with ADR / IMDG / IATA

ADR	IMDG	IATA
14.1. UN number or ID number		
UN 1993	UN 1993	UN 1993
14.2. UN proper shipping name		
FLAMMABLE LIQUID, N.O.S.	FLAMMABLE LIQUID, N.O.S.	Flammable liquid, n.o.s.
Transport document description		
UN 1993 FLAMMABLE LIQUID, N.O.S., 3, III, (D/E), ENVIRONMENTALLY HAZARDOUS	UN 1993 FLAMMABLE LIQUID, N.O.S., 3, III, MARINE POLLUTANT/ENVIRONMENTALLY HAZARDOUS	UN 1993 Flammable liquid, n.o.s., 3, III, ENVIRONMENTALLY HAZARDOUS
14.3. Transport hazard class(es)		
3	3	3
		
14.4. Packing group		
III	III	III
14.5. Environmental hazards		
Dangerous for the environment: Yes	Dangerous for the environment: Yes Marine pollutant: Yes EmS-No. (Fire): F-E EmS-No. (Spillage): S-E	Dangerous for the environment: Yes
No supplementary information available		

14.6. Special precautions for user

Overland transport

Classification code (ADR) : F1
Special provisions (ADR) : 274, 601
Limited quantities (ADR) : 5I

Etonogestrel impurity mixture

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Excepted quantities (ADR)	: E1
Packing instructions (ADR)	: P001, IBC03, LP01, R001
Mixed packing provisions (ADR)	: MP19
Portable tank and bulk container instructions (ADR)	: T4
Portable tank and bulk container special provisions (ADR)	: TP1, TP29
Tank code (ADR)	: LGBF
Vehicle for tank carriage	: FL
Transport category (ADR)	: 3
Special provisions for carriage - Packages (ADR)	: V12
Special provisions for carriage - Operation (ADR)	: S2
Hazard identification number (Kemler No.)	: 30
Orange plates	:



Tunnel restriction code (ADR) : D/E

Transport by sea

Special provisions (IMDG)	: 223, 274, 955
Limited quantities (IMDG)	: 5 L
Excepted quantities (IMDG)	: E1
Packing instructions (IMDG)	: LP01, P001
IBC packing instructions (IMDG)	: IBC03
Tank instructions (IMDG)	: T4
Tank special provisions (IMDG)	: TP1, TP29
Stowage category (IMDG)	: A

Air transport

PCA Excepted quantities (IATA)	: E1
PCA Limited quantities (IATA)	: Y344
PCA limited quantity max net quantity (IATA)	: 10L
PCA packing instructions (IATA)	: 355
PCA max net quantity (IATA)	: 60L
CAO packing instructions (IATA)	: 366
CAO max net quantity (IATA)	: 220L
Special provisions (IATA)	: A3
ERG code (IATA)	: 3L

14.7. Maritime transport in bulk according to IMO instruments

Not applicable

SECTION 15: Regulatory information

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

EU-Regulations

REACH Annex XVII (Restriction List)

Contains no substance(s) listed on REACH Annex XVII (Restriction Conditions)

REACH Annex XIV (Authorisation List)

Contains no substance(s) listed on REACH Annex XIV (Authorisation List)

REACH Candidate List (SVHC)

Contains no substance(s) listed on the REACH Candidate List

Ozone Regulation (1005/2009)

Contains no substance(s) listed on the Ozone Depletion list (Regulation EU 1005/2009 on substances that deplete the ozone layer)

Council Regulation (EC) for the control of dual-use items

Contains no substance subject to the COUNCIL REGULATION (EC) for the control of dual-use items

Etonogestrel impurity mixture

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Explosives Precursors Regulation (EU 2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

Drug Precursors Regulation (EC 273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

15.2. Chemical safety assessment

No additional information available

SECTION 16: Other information

Indication of changes		
Section	Changed item	Comments
	Packing instructions (ADR)	Modified
	IBC packing instructions (IMDG)	Modified
	Excepted quantities (IMDG)	Modified
	Special provisions (IMDG)	Modified
	Special provisions for carriage - Operation (ADR)	Modified
	Tank code (ADR)	Modified
	Portable tank and bulk container special provisions (ADR)	Modified
	Portable tank and bulk container instructions (ADR)	Modified
	Classification code (RID)	Added
	Special provisions for carriage - Packages (ADR)	Added
	ERG code (IATA)	Modified
	CAO max net quantity (IATA)	Modified
	CAO packing instructions (IATA)	Modified
	PCA max net quantity (IATA)	Modified
	PCA packing instructions (IATA)	Modified
	PCA limited quantity max net quantity (IATA)	Modified
	PCA Limited quantities (IATA)	Modified
	PCA Excepted quantities (IATA)	Modified
	Limited quantities (IMDG)	Modified
	Stowage category (IMDG)	Modified
	Tank special provisions (IMDG)	Modified
	Tank instructions (IMDG)	Modified
	UN-No. (RID)	Added
	Number of blue cones/lights (ADN)	Added
	Ventilation (ADN)	Added
	Equipment required (ADN)	Added
	Carriage permitted (ADN)	Added

Etonogestrel impurity mixture

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Indication of changes		
Section	Changed item	Comments
	Excepted quantities (ADN)	Added
	Limited quantities (ADN)	Added
	Danger labels (ADN)	Added
	Classification code (ADN)	Added
	Proper Shipping Name (RID)	Added
	Hazard identification number (RID)	Added
	Colis express (express parcels) (RID)	Added
	Special provisions for carriage – Packages (RID)	Added
	Transport category (RID)	Added
	Tank codes for RID tanks (RID)	Added
	Portable tank and bulk container special provisions (RID)	Added
	Portable tank and bulk container instructions (RID)	Added
	Mixed packing provisions (RID)	Added
	Packing instructions (RID)	Added
	Excepted quantities (RID)	Added
	Limited quantities (RID)	Added
	Special provisions (RID)	Added
	Packing group (RID)	Added
	Supersedes version of	Added
	Revision date	Added
1.2	Restrictions on use	Modified
1.2	Use of the substance/mixture	Modified
1.2	Main use category	Removed
2.1	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Modified
2.1	Adverse physicochemical, human health and environmental effects	Modified
2.3	Other information	Added
4.1	First-aid measures general	Added
4.1	First-aid measures after skin contact	Modified
4.1	First-aid measures after inhalation	Modified
4.1	First-aid measures after ingestion	Modified
4.1	First-aid measures after eye contact	Modified
4.2	Symptoms/effects after skin contact	Removed
4.2	Symptoms/effects after inhalation	Removed
4.2	Symptoms/effects after eye contact	Modified
4.3	Other medical advice or treatment	Removed

Etonogestrel impurity mixture

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Indication of changes		
Section	Changed item	Comments
5.1	Unsuitable extinguishing media	Added
5.1	Suitable extinguishing media	Modified
5.2	Hazardous decomposition products in case of fire	Added
5.2	Fire hazard	Removed
5.3	Protection during firefighting	Added
5.3	Firefighting instructions	Modified
6.1	Protective equipment	Added
6.1	Emergency procedures	Added
6.1	General measures	Modified
6.2	Environmental precautions	Added
6.3	For containment	Added
6.3	Methods for cleaning up	Modified
6.4	Reference to other sections (8, 13)	Added
7.1	Additional hazards when processed	Removed
7.1	Precautions for safe handling	Modified
7.1	Hygiene measures	Modified
7.2	Packaging materials	Added
7.2	Technical measures	Removed
7.2	Storage conditions	Modified
7.3	Specific end uses	Removed
8.2	Appropriate engineering controls	Modified
8.2	Skin and body protection	Modified
8.2	Respiratory protection	Modified
8.2	Hand protection	Modified
8.2	Eye protection	Modified
9	Flammability	Added
9	Odour	Removed
10.1	Reactivity	Modified
10.5	Incompatible materials	Removed
10.6	Hazardous decomposition products	Removed
11.1	ATE CLP (vapours)	Added
11.1	ATE CLP (gases)	Added
11.1	ATE CLP (dust,mist)	Modified
12.1	Ecology - general	Removed
13.1	Regional waste regulation	Removed
14.1	UN-No. (ADN)	Added
14.2	Proper Shipping Name (ADN)	Added

Etonogestrel impurity mixture

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Indication of changes		
Section	Changed item	Comments
14.3	Danger labels (RID)	Added
14.4	Packing group (IATA)	Modified
14.4	Packing group (IMDG)	Modified
14.4	Packing group (ADN)	Added
14.4	Packing group (ADR)	Modified
14.6	Limited quantities (ADR)	Modified
14.6	Excepted quantities (ADR)	Modified
14.6	Transport category (ADR)	Modified
14.6	Special provisions (ADR)	Modified
14.6	Packing instructions (IMDG)	Modified
14.6	Special provisions (ADN)	Added
14.6	Hazard identification number (Kemler No.)	Modified

Full text of H- and EUH-statements:	
Acute Tox. 4 (Dermal)	Acute toxicity (dermal), Category 4
Acute Tox. 4 (Inhalation)	Acute toxicity (inhal.), Category 4
Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Aquatic Chronic 1	Hazardous to the aquatic environment – Chronic Hazard, Category 1
Carc. 2	Carcinogenicity, Category 2
ED ENV 1	Endocrine disruptor for the environment, Category 1
ED HH 1	Endocrine disruptor for human health, Category 1
EUH380	May cause endocrine disruption in humans.
EUH430	May cause endocrine disruption in the environment.
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
Flam. Liq. 2	Flammable liquids, Category 2
H225	Highly flammable liquid and vapour.
H302	Harmful if swallowed.
H312	Harmful in contact with skin.
H319	Causes serious eye irritation.
H332	Harmful if inhaled.
H351	Suspected of causing cancer.
H360	May damage fertility or the unborn child.
H372	Causes damage to organs through prolonged or repeated exposure.
H410	Very toxic to aquatic life with long lasting effects.
Repr. 1A	Reproductive toxicity, Category 1A
STOT RE 1	Specific target organ toxicity – Repeated exposure, Category 1

Etonogestrel impurity mixture

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:

Flam. Liq. 2	H225	Calculation method
Acute Tox. 4 (Oral)	H302	Calculation method
Acute Tox. 4 (Dermal)	H312	Calculation method
Acute Tox. 4 (Inhalation)	H332	Calculation method
Eye Irrit. 2	H319	Calculation method
Aquatic Chronic 1	H410	Calculation method

Safety Data Sheet (SDS), EU

DISCLAIMER OF LIABILITY The information in this SDS was obtained from sources which we believe are reliable. However, the information is provided without any warranty, express or implied, regarding its correctness. The conditions or methods of handling, storage, use or disposal of the product are beyond our control and may be beyond our knowledge. For this and other reasons, we do not assume responsibility and expressly disclaim liability for loss, damage or expense arising out of or in any way connected with the handling, storage, use or disposal of the product. This SDS was prepared and is to be used only for this product. If the product is used as a component in another product, this SDS information may not be applicable. This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.