

Etonogestrel impurity mixture

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878
Issue date: 25/03/2024 Version: 1.0

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

1.2.1. Relevant identified uses

Main use category : The product is intended for research, analysis and scientific education.
Use of the substance/mixture : For professional use only
Function or use category : Laboratory chemicals

1.2.2. Uses advised against

Restrictions on use : Do not use : Ingestion, Inhalation, Dermal

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 (inhalation:dust,mist) Category 4	H332
Serious eye damage/eye irritation, Category 2	H319
Full text of H- and EUH-statements: see section 16	

Adverse physicochemical, human health and environmental effects

Expert judgement and weight of evidence determination.

2.2. Label elements

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

Hazard pictograms (CLP)



GHS02

GHS07

Signal word (CLP)

: Danger

Contains

: Acetonitrile

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.

Precautionary statements (CLP)

: P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources.
No smoking.

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- 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.
- 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.
- 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 ≥ 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 %

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

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

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 after inhalation : Move to fresh air. Allow affected person to breathe fresh air.

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First-aid measures after skin contact	: Wipe off as much as possible (using a clean, soft, absorbent material). Wash with plenty of water and detergent.
First-aid measures after eye contact	: Rinse with water while holding the eyes wide open.
First-aid measures after ingestion	: Rinse mouth.

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

Symptoms/effects after inhalation	: Insufficient data available.
Symptoms/effects after skin contact	: Insufficient data available.
Symptoms/effects after eye contact	: Insufficient data available.

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

Get medical advice/attention. If possible show this sheet, if not available show packaging or label.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	: Extinguishing blanket.
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5.2. Special hazards arising from the substance or mixture

Fire hazard	: See Heading 2.2.
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5.3. Advice for firefighters

Firefighting instructions	: Use extinguishing media appropriate for surrounding fire.
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SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures	: Avoid any direct contact with the product. Do not breathe dust/fume/gas/mist/vapours/spray.
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6.1.1. For non-emergency personnel

No additional information available

6.1.2. For emergency responders

No additional information available

6.2. Environmental precautions

No additional information available

6.3. Methods and material for containment and cleaning up

Methods for cleaning up	: Ensure waste is collected and contained. Clean thoroughly.
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6.4. Reference to other sections

No additional information available

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Additional hazards when processed	: The attention of the user is drawn to the risks possibly incurred by using the product for any other purpose than that for which it was intended.
Precautions for safe handling	: Material should be handled with caution. Avoid any direct contact with the product.
Hygiene measures	: Handle in accordance with good industrial hygiene and safety procedures.

7.2. Conditions for safe storage, including any incompatibilities

Technical measures	: Comply with applicable regulations.
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Storage conditions : Store locked up.

7.3. Specific end use(s)

See Heading 1.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1 National occupational exposure and biological limit values

No additional information available

8.1.2. Recommended monitoring procedures

No additional information available

8.1.3. Air contaminants formed

No additional information available

8.1.4. DNEL and PNEC

No additional information available

8.1.5. Control banding

No additional information available

8.2. Exposure controls

8.2.1. Appropriate engineering controls

Appropriate engineering controls:

Keep in a well-ventilated room. Use only in a exhaust booth with integrated air filter. High efficiency particulate air filter (HEPA filter).

8.2.2. Personal protection equipment

8.2.2.1. Eye and face protection

Eye protection:

Safety glasses. DIN EN 166

8.2.2.2. Skin protection

Skin and body protection:

Use chemically protective clothing. DIN EN 13034

Hand protection:

Chemically resistant protective gloves. ISO 374-1

8.2.2.3. Respiratory protection

Respiratory protection:

Dust production: dust mask with filter type P3. DIN EN 140 & 149. Liquid product : Aerosol mask. Wear breathing apparatus if exposed to vapours/dusts/aerosols

8.2.2.4. Thermal hazards

No additional information available

8.2.3. Environmental exposure controls

No additional information available

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Colour	: Not available
Odour	: Not applicable.
Odour threshold	: Not available

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Melting point	: Not available
Freezing point	: Not available
Boiling point	: Not available
Flammability	: Not available
Explosive limits	: Not available
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

9.2.1. Information with regard to physical hazard classes

No additional information available

9.2.2. Other safety characteristics

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Stable under normal conditions.

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

None under normal use. See Section 7.

10.6. Hazardous decomposition products

When heated to decomposition, emits dangerous fumes.

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.

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ATE CLP (oral)	500.05 mg/kg bodyweight
ATE CLP (dermal)	1100.11 mg/kg bodyweight
ATE CLP (dust,mist)	1.5 mg/l/4h

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)
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Serious eye damage/irritation : Causes serious eye irritation.

Acetonitrile (75-05-8)

pH	6.5 – 7.5 at 50g/l (20°C)
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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)

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

11.2. Information on other hazards

No additional information available

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : Hazardous waste. Use suitable disposal containers.

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

Not rapidly degradable

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

Acetonitrile (75-05-8)

Partition coefficient n-octanol/water (Log Pow)	-0.34
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12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Endocrine disrupting properties

No additional information available

12.7. Other adverse effects

No additional information available

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SECTION 13: Disposal considerations

13.1. Waste treatment methods

Regional waste regulation : Dispose in a safe manner in accordance with local/national regulations.

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, II, (D/E)	UN 1993 FLAMMABLE LIQUID, N.O.S., 3, II	UN 1993 Flammable liquid, n.o.s., 3, II
14.3. Transport hazard class(es)		
3	3	3
		
14.4. Packing group		
II	II	II
14.5. Environmental hazards		
Dangerous for the environment: No	Dangerous for the environment: No Marine pollutant: No	Dangerous for the environment: No
No supplementary information available		

14.6. Special precautions for user

Overland transport

Classification code (ADR) : F1
Special provisions (ADR) : 274, 601, 640C
Limited quantities (ADR) : 1I
Excepted quantities (ADR) : E2
Packing instructions (ADR) : P001
Mixed packing provisions (ADR) : MP19
Portable tank and bulk container instructions (ADR) : T7
Portable tank and bulk container special provisions (ADR) : TP1, TP8, TP28
Tank code (ADR) : L1.5BN
Vehicle for tank carriage : FL
Transport category (ADR) : 2
Special provisions for carriage - Operation (ADR) : S2, S20
Hazard identification number (Kemler No.) : 33

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Orange plates	:	<div><div>33</div><div>1993</div></div>
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Tunnel restriction code (ADR) : D/E

Transport by sea

Special provisions (IMDG)	:	274
Limited quantities (IMDG)	:	1 L
Excepted quantities (IMDG)	:	E2
Packing instructions (IMDG)	:	P001
IBC packing instructions (IMDG)	:	IBC02
Tank instructions (IMDG)	:	T7
Tank special provisions (IMDG)	:	TP1, TP28, TP8
EmS-No. (Fire)	:	F-E
EmS-No. (Spillage)	:	S-E
Stowage category (IMDG)	:	B

Air transport

PCA Excepted quantities (IATA)	:	E2
PCA Limited quantities (IATA)	:	Y341
PCA limited quantity max net quantity (IATA)	:	1L
PCA packing instructions (IATA)	:	353
PCA max net quantity (IATA)	:	5L
CAO packing instructions (IATA)	:	364
CAO max net quantity (IATA)	:	60L
Special provisions (IATA)	:	A3
ERG code (IATA)	:	3H

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

15.1.1. 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

PIC Regulation (Prior Informed Consent)

Not applicable.

POP Regulation (Persistent Organic Pollutants)

Not applicable.

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)

Explosives Precursors Regulation (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 (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)

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15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No additional information available

SECTION 16: Other information

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
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.

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:dust,mist)	H332	Calculation method
Eye Irrit. 2	H319	Calculation method

Safety Data Sheet (SDS), EU

DISCLAIMER OF LIABILITY The EDQM has created this SDS as a downstream user for regulatory compliance to rules applicable to chemicals only. This article is intended only for small-volume laboratory analysis and other routine testing prescribed in the pharmacopoeia or EDQM study protocol, under controlled conditions and by professionals only. Any other use of this article or the SDS information is the sole responsibility of the user. This substance is present in articles in quantities totalling under 10 kg per year. There is no human or environmental exposure under intended and foreseeable conditions of use. The user has the responsibility for handling, storage, use conditions and disposal of this article and for any use of the information in this SDS. The information has been obtained from suppliers and is without any warranty, express or implied, regarding its correctness. 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 article.