



CONSEIL DE L'EUROPE

Testosterone enantate impurity H

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878 Issue date: 19/06/2024 Version: 1.0

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

1.1. Product identifier

Product form Substance name Chemical name CAS-No. Product code	 Substance Testosterone enantate impurity H Androst-5-ene-3beta,17beta-diyl diheptanoate 162890-98-4 202400290
1.2. Relevant identified uses of the substa	ance or mixture and uses advised against
1.2.1. Relevant identified uses	
Main use category Use of the substance/mixture Function or use category	 The product is intended for research, analysis and scientific education. For professional use only 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 da	ata 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]

Acute toxicity (oral), Category 4	H302
Carcinogenicity, Category 2	H351
Reproductive toxicity, Category 1B	H360FD
Reproductive toxicity, Additional category, Effects on or via lactation	H362
Hazardous to the aquatic environment – Chronic Hazard, Category 4	H413
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. 1272/20	008 [CLP]
Hazard pictograms (CLP)	GHS07 GHS08
5 (-)	 Danger H302 - Harmful if swallowed. H351 - Suspected of causing cancer. H360FD - May damage fertility. May damage the unborn child.

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	H362 - May cause harm to breast-fed children.
	H413 - May cause long lasting harmful effects to aquatic life.
Precautionary statements (CLP)	: P201 - Obtain special instructions before use.
	P202 - Do not handle until all safety precautions have been read and understood.
	P260 - Do not breathe dust/fume/gas/mist/vapours/spray.
	P263 - Avoid contact during pregnancy and while nursing.
	P264 - Wash hands, forearms and face thoroughly after handling.
	P270 - Do not eat, drink or smoke when using this product.
	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.
	P308+P313 - IF exposed or concerned: Get medical advice/attention.
	P330 - Rinse mouth.
	P405 - Store locked up.
	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.
Hazard pictograms (CLP)	
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GHS08

2.3. Other hazards

No additional information available

SECTION 3: Composition/information on ingredients

3.1. Substances

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Androst-5-ene-3beta,17beta-diyl diheptanoate	CAS-No.: 162890-98-4	≤ 100	Acute Tox. 4 (Oral), H302 Carc. 2, H351 Repr. 1B, H360FD Lact., H362 Aquatic Chronic 4, H413

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

3.2. Mixtures

Not applicable

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.
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. Prolonged medical observation may be indicated.
4.2. Most important symptoms and ef	fects, both acute and delayed
Symptoms/effects Symptoms/effects after inhalation	Delayed adverse effects possible.Insufficient data available.

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Symptoms/effects after skin contact Symptoms/effects after eye contact	Insufficient data available.Insufficient data available.
4.3. Indication of any immediate med	ical 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.
5.2. Special hazards arising from the su	bstance or mixture
Fire hazard	: See Heading 2.2.
5.3. Advice for firefighters	
Firefighting instructions	: Use extinguishing media appropriate for surrounding fire.
SECTION 6: Accidental release mea	sures
6.1. Personal precautions, protective eq	uipment and emergency procedures
General measures	: Avoid any direct contact with the product. Do not breathe dust/fume/gas/mist/vapours/spray.
6.1.1. For non-emergency personnel Emergency procedures	: Wear suitable protective clothing, gloves and eye or face protection.
6.1.2. For emergency responders No additional information available	
6.2. Environmental precautions	
No additional information available	
6.3. Methods and material for containme	ent and cleaning up
Methods for cleaning up	: Ensure waste is collected and contained. Clean thoroughly. Wash the non-recoverable remainder with : Sodium hypochlorite solution.
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 numbers than that for which it was intended
Precautions for safe handling	other purpose than that for which it was intended.Material should be handled with caution. Avoid any direct contact with the product. Material should be handled in a laboratory hood whenever possible.
Hygiene measures	: Handle in accordance with good industrial hygiene and safety procedures.
7.2. Conditions for safe storage, includi	ng any incompatibilities
Technical measures Storage conditions	: Comply with applicable regulations. : Store locked up.

7.3. Specific end use(s)

See Heading 1.

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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	: Solid	
Colour	: Not available	
Odour	: Not applicable.	
Odour threshold	: Not available	
Melting point	: Not available	
Freezing point	: Not available	
Boiling point	: Not available	
Flammability	: Not available	

Lower explosion limit

Explosive limits

: Not applicable

: Not applicable

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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)	: Not classified (Lack of data)
Acute toxicity (inhalation)	: Not classified (Lack of data)
Skin corrosion/irritation	: Not classified (Lack of data)
Serious eye damage/irritation	: Not classified (Lack of data)
Respiratory or skin sensitisation	: Not classified (Lack of data)
Germ cell mutagenicity	: Not classified (Based on available data, the classification criteria are not met)
Carcinogenicity	: Suspected of causing cancer.
Reproductive toxicity	: May damage fertility. May damage the unborn child. May cause harm to breast-fed children.
STOT-single exposure	: Not classified (Lack of data)

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STOT-repeated exposure	:	Not classified (Lack of data)
Aspiration hazard	:	Not classified (Technical impossibility to obtain the data)

11.2. Information on other hazards

No additional information available

SECTION 12: Ecological information	
12.1. Toxicity	
Hazardous to the aquatic environment, short-term : Not class (acute)	s waste. Use suitable disposal containers. fied (Based on available data, the classification criteria are not met) e long lasting harmful effects to aquatic life.
12.2. Persistence and degradability	
No additional information available	
12.3. Bioaccumulative potential	
No additional information available	
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	

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	ΙΑΤΑ		
14.1. UN number or ID number				
Not applicable	Not applicable	Not applicable		
14.2. UN proper shipping name				
Not applicable	Not applicable	Not applicable		
14.3. Transport hazard class(es)				
Not applicable	Not applicable	Not applicable		

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ADR	IMDG	ΙΑΤΑ
14.4. Packing group		
Not applicable	Not applicable	Not applicable
14.5. Environmental ha	zards	
Not applicable	Not applicable	Not applicable
No supplementary information available		
14.6. Special precautions for user		

Overland transport

Not applicable

Transport by sea

Not applicable

Air transport

Not applicable

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)

Not listed on REACH Annex XVII

REACH Annex XIV (Authorisation List)

Not listed on REACH Annex XIV (Authorisation List)

REACH Candidate List (SVHC)

Not listed on the REACH Candidate List

PIC Regulation (Prior Informed Consent)

Not applicable.

POP Regulation (Persistent Organic Pollutants)

Not applicable.

Ozone Regulation (1005/2009)

Not listed on the Ozone Depletion list (Regulation EU 1005/2009)

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)

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No additional information available

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SECTION 16: Other information		
Full text of H- and EUH-statements:		
Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4	
Aquatic Chronic 4	Hazardous to the aquatic environment – Chronic Hazard, Category 4	
Carc. 2	Carcinogenicity, Category 2	
H302	Harmful if swallowed.	
H351	Suspected of causing cancer.	
H360FD	May damage fertility. May damage the unborn child.	
H362	May cause harm to breast-fed children.	
H413	May cause long lasting harmful effects to aquatic life.	
Lact.	Reproductive toxicity, Additional category, Effects on or via lactation	
Repr. 1B	Reproductive toxicity, Category 1B	

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.