



CONSEIL DE L'EUROPE

3-Oxoandrost-4-en-17β-yl 4-methylpentanoate

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878 Issue date: 03/04/2023 Version: 1.0

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

1.1. Product identifier Product form : Substance Substance name : 3-Oxoandrost-4-en-17β-yl 4-methylpentanoate Product code : 202200109 Synonyms : Testosterone Isocaproate 1.2. Relevant identified uses of the substance or mixture and uses advised against 1.2.1. Relevant identified uses : The product is intended for research, analysis and scientific education. Main use category 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]	

Acute toxicity (oral), Category 4	H302
Carcinogenicity, Category 2	H351
Reproductive toxicity, Category 1A	H360Df
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)	GHS07 GHS08
Signal word (CLP)	-
3	: Danger
Hazard statements (CLP)	 H302 - Harmful if swallowed. H351 - Suspected of causing cancer. H360Df - May damage the unborn child. Suspected of damaging fertility.
Precautionary statements (CLP)	: P201 - Obtain special instructions before use.
	P202 - Do not handle until all safety precautions have been read and understood. P264 - Wash hands, forearms and face thoroughly after handling.
	P270 - Do not eat, drink or smoke when using this product.

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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)



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]
3-Oxoandrost-4-en-17β-yl 4-methylpentanoate	-	≤ 100	Acute Tox. 4 (Oral), H302 (ATE=500 mg/kg bodyweight) Carc. 2, H351 Repr. 1A, H360Df

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. Specific medical surveillance. Prolonged medical observation may be indicated. 4.2. Most important symptoms and effects, both acute and delayed Symptoms/effects : Delayed adverse effects possible. : Insufficient data available. Symptoms/effects after inhalation : Insufficient data available. Symptoms/effects after skin contact : Insufficient data available. Symptoms/effects after eye contact Symptoms/effects after ingestion : Symptoms may include dizziness, headache, nausea and loss of coordination.

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. Active substance. Pharmaceutical.

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SECTION 5: Firefighting measures			
5.1. Extinguishing media			
Suitable extinguishing media	: Extinguishing blanket.		
5.2. Special hazards arising from the substance 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 measures			
6.1. Personal precautions, protective e	quipment 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 containm	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. Poterance to other costions			

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. 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, including any incompatibilities			
Technical measures Storage conditions	Comply with applicable regulations.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

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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	
Explosive limits	: Not applicable	
Lower explosion limit	: Not applicable	
Upper explosion limit	: Not applicable	
Flash point	: Not applicable	
Auto-ignition temperature	: Not applicable	
Decomposition temperature	: Not available	
рН	: Not available	
pH solution	: Not available	
Viscosity, kinematic	: Not applicable	

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Solubility	: Water: < 0.1 g/l
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 applicable
Particle size	: Not available

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

ECTION 10: Stability and reactivity
.1. Reactivity
ble under normal conditions.
.2. Chemical stability
additional information available
.3. Possibility of hazardous reactions
additional information available
.4. Conditions to avoid
additional information available
.5. Incompatible materials
ne under normal use. See Section 7.
.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)	cute toxicity (dermal) : Not classified		
Acute toxicity (inhalation) : Not classified			
Skin corrosion/irritation	· Not classified		

Skin corrosion/irritation	-	Not classified
Serious eye damage/irritation	:	Not classified
Respiratory or skin sensitisation	:	Not classified
Germ cell mutagenicity	:	Not classified
Carcinogenicity	:	Suspected of causing cancer.
Reproductive toxicity	:	May damage the unborn child. Suspected of damaging fertility.
STOT-single exposure	:	Not classified
STOT-repeated exposure	:	Not classified
Aspiration hazard	:	Not classified

11.2. Information on other hazards

No additional information available

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SECTION 12: Ecological information	
12.1. Toxicity	
Ecology - general Hazardous to the aquatic environment, short-term (acute) Hazardous to the aquatic environment, long-term (chronic) Not rapidly degradable	 Hazardous waste. Use suitable disposal containers. Not classified Not classified
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 legislation (waste)

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

n 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	
14.4. Packing group			
Not applicable	Not applicable	Not applicable	
14.5. Environmental hazards			
Not applicable	Not applicable	Not applicable	

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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

SECTION 16: Other information

Indication of changes:

Classification of the substance or mixture.

Full text of H- and EUH-statements:	
Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Carc. 2	Carcinogenicity, Category 2

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Full text of H- and EUH-statements:	
H302	Harmful if swallowed.
H351	Suspected of causing cancer.
H360Df	May damage the unborn child. Suspected of damaging fertility.
Repr. 1A	Reproductive toxicity, Category 1A

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.