Safety Data Sheet

according to WHS Regulations

Printing date 03.05.2023 Revision: 03.05.2023 Version number 1.0

1 Identification

· Product identifier

· Trade name: Oxandrolone · Article number: 102399

· CAS Number: 53-39-4

• **EC number:** 200-172-9

- · Relevant identified uses of the substance or mixture and uses advised against No further relevant information available.
- · Application of the substance / the mixture Additive for cosmetic or pharmaceutic preparations
- · Details of the supplier of the safety data sheet
- · Manufacturer/Supplier:

Fagron Services B.V.

Molenwerk 13, UITGEEST, 1911DB

Netherlands

Phone: +31251361400

Supplier Azelis Australia Suite 217 117 Old Pittwater Road Brookvale

NSW 2100 Australia

Phone: +61 0299392188 Fax: +61 0299392799 e-mail: info@azelis.com.au

- · Further information obtainable from: info@fagron.com.au
- · Emergency telephone number:

In case of emergency, please call your local poisons:

Emergency Australia: 13 11 26

Emergency NZ: 0800 764 766 (0800 POISON)

1800 127 406 (24 h, Australia) | +64 4 917 9888 (24 h, Worldwide) CareChem 24x7 : EUROPE: +44 1235 239670 | USA: +1 202 464 2554 | CANADA - +1 800 579 7421 (Toll Free)| ASIA - +65 3158 1074 | MOROCCO - +44 1235 239671 | REST OF THE WORLD - +44 1865 407333 (English only)

2 Hazard(s) Identification

· Classification of the substance or mixture

Acute Tox. 4 H302 Harmful if swallowed.

Resp. Sens. 1 H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Skin Sens. 1 H317 May cause an allergic skin reaction.

Carc. 1B H350 May cause cancer.

Repr. 1A H360 May damage fertility or the unborn child.

- Label elements
- GHS label elements

The substance is classified and labelled according to the Globally Harmonised System (GHS).

(Contd. on page 2)

AUS



Printing date 03.05.2023 Revision: 03.05.2023 Version number 1.0

Trade name: Oxandrolone

Hazard pictograms

(Contd. of page 1)





Signal word Danger

· Hazard statements

Harmful if swallowed.

May cause allergy or asthma symptoms or breathing difficulties if inhaled.

May cause an allergic skin reaction.

May cause cancer.

May damage fertility or the unborn child.

· Precautionary statements

Avoid breathing dust/fume/gas/mist/vapours/spray.

Wear protective gloves/protective clothing/eye protection/face protection.

Wear respiratory protection.

If experiencing respiratory symptoms: Call a POISON CENTER/doctor.

Store locked up.

Dispose of contents/container in accordance with local/regional/national/international regulations.

- · Other hazards
- · Results of PBT and vPvB assessment
- · **PBT**: Not applicable.
- · vPvB: Not applicable.

3 Composition and Information on Ingredients

· Chemical characterisation: Substances

· CAS No. Description CAS: 53-39-4 Oxandrolone · Identification number(s) **EC number:** 200-172-9

4 First Aid Measures

- · Description of first aid measures
- General information:

Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.

After inhalation:

Supply fresh air and to be sure call for a doctor.

In case of unconsciousness place patient stably in side position for transportation.

· After skin contact:

Immediately wash with water and soap and rinse thoroughly.

If skin irritation continues, consult a doctor.

· After eve contact:

Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

- · After swallowing: Do not induce vomiting; call for medical help immediately.
- · Information for doctor:
- · Most important symptoms and effects, both acute and delayed

No further relevant information available.

(Contd. on page 3)



Printing date 03.05.2023 Revision: 03.05.2023

Version number 1.0

Trade name: Oxandrolone

(Contd. of page 2)

· Indication of any immediate medical attention and special treatment needed No further relevant information available.

5 Fire Fighting Measures

- · Extinguishing media
- Suitable extinguishing agents:

Use fire extinguishing methods suitable to surrounding conditions.

Water spray

Foam

Carbon dioxide

Fire-extinguishing powder

Special hazards arising from the substance or mixture

Formation of toxic gases is possible during heating or in case of fire.

- Advice for firefighters
- · Protective equipment:

Wear self-contained respiratory protective device.

Wear fully protective suit.

6 Accidental Release Measures

- · Personal precautions, protective equipment and emergency procedures Avoid formation of dust.
- · Environmental precautions: Do not allow to enter sewers/ surface or ground water.
- · Methods and material for containment and cleaning up:

Ensure adequate ventilation.

Pick up mechanically.

Dispose of the material collected according to regulations.

Dispose contaminated material as waste according to item 13.

Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

7 Handling and Storage

- · Handling:
- · Precautions for safe handling Ensure good ventilation/exhaustion at the workplace.
- · Information about fire and explosion protection: No special measures required.
- · Conditions for safe storage, including any incompatibilities
- · Storage:
- · Requirements to be met by storerooms and receptacles: No special requirements.
- Information about storage in one common storage facility: Not required.
- Further information about storage conditions:

Keep container tightly sealed.

Protect from exposure to the light.

· Specific end use(s) No further relevant information available.

8 Exposure controls and personal protection

- · Additional information about design of technical facilities: No further data; see item 7.
- · Control parameters
- · Ingredients with limit values that require monitoring at the workplace: Not required.

(Contd. on page 4)

Printing date 03.05.2023 Revision: 03.05.2023

Version number 1.0

Trade name: Oxandrolone

(Contd. of page 3)

- · Additional information: The lists valid during the making were used as basis.
- Exposure controls
- · Personal protective equipment:
- General protective and hygienic measures:

Keep away from foodstuffs, beverages and feed.

Immediately remove all soiled and contaminated clothing

Wash hands before breaks and at the end of work.

Store protective clothing separately.

Respiratory protection:

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

Protection of hands:



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

Material of gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.

· Penetration time of glove material

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

· Eye protection:



Tightly sealed goggles

Body protection: Protective work clothing

9 Physical and Chemical Properties

- · Information on basic physical and chemical properties
- · General Information
- · Appearance:

Form: Crystalline powder

Colour: White · Odour: Odourless · Odour threshold: Not determined.

· pH-value: Not applicable.

· Change in condition

Melting point/freezing point: Undetermined. Initial boiling point and boiling range: Undetermined.

· Flash point: Not applicable.

· Flammability (solid, gas): Product is not flammable.

(Contd. on page 5)



Safety Data Sheet according to WHS Regulations

Printing date 03.05.2023 Revision: 03.05.2023 Version number 1.0

Trade name: Oxandrolone

	(Contd. of pag
Decomposition temperature:	Not determined.
Auto-ignition temperature:	Not determined.
Explosive properties:	Product does not present an explosion hazard.
Explosion limits:	
Lower:	Not determined.
Upper:	Not determined.
Vapour pressure:	Not applicable.
Density:	Not determined.
Relative density	Not determined.
Vapour density	Not applicable.
Evaporation rate	Not applicable.
Solubility in / Miscibility with	
water:	Not determined.
Partition coefficient: n-octanol/water:	Not determined.
Viscosity:	
Dynamic:	Not applicable.
Kinematic:	Not applicable.
Other information	No further relevant information available.

10 Stability and Reactivity

- · Reactivity No further relevant information available.
- · Chemical stability
- Thermal decomposition / conditions to be avoided:

No decomposition if used according to specifications.

- · Possibility of hazardous reactions Reacts with oxidising agents.
- · Conditions to avoid No further relevant information available.
- · Incompatible materials: No further relevant information available.
- Hazardous decomposition products:

Carbon monoxide and carbon dioxide

Hydrogen

Oxygen

11 Toxicological Information

- · Information on toxicological effects
- · Acute toxicity
- · LD/LC50 values relevant for classification:

Oral LD50 1832 mg/kg (mouse)

· Respiratory or skin sensitisation

Sensitisation possible through inhalation.

Sensitisation possible through skin contact.

- Additional toxicological information:
- · CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)

Carc. 1B, Repr. 1A

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(Contd. on page 6)



Printing date 03.05.2023 Revision: 03.05.2023 Version number 1.0

Trade name: Oxandrolone

(Contd. of page 5)

12 Ecological Information

- · Toxicity
- · Aquatic toxicity: No further relevant information available.
- · Persistence and degradability No further relevant information available.
- · Behaviour in environmental systems:
- · Bioaccumulative potential No further relevant information available.
- · Mobility in soil No further relevant information available.
- · Additional ecological information:
- · General notes:

Do not allow product to reach ground water, water course or sewage system, even in small quantities.

Water hazard class 3 (German Regulation) (Self-assessment): extremely hazardous for water Danger to drinking water if even extremely small quantities leak into the ground.

- Results of PBT and vPvB assessment
- · PBT: Not applicable.
- · vPvB: Not applicable.
- Other adverse effects No further relevant information available.

13 Disposal considerations

- · Waste treatment methods
- · Recommendation

Must not be disposed together with household garbage. Do not allow product to reach sewage system.

- Uncleaned packaging:
- · **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

· UN-Number	
· ADG, IMDG, IATA	not regulated
· UN proper shipping name · ADG, IMDG, IATA	not regulated
· Transport hazard class(es)	
· ADG, ADN, IMDG, IATA	
· Class	not regulated
· Packing group	
· ADG, IMDG, IATA	not regulated
· Environmental hazards:	Not applicable.
· Special precautions for user	Not applicable.
Transport in bulk according to Anne	ex II of
Marpol and the IBC Code	Not applicable.
· UN "Model Regulation":	not regulated

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(Contd. on page 7)



Safety Data Sheet

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Printing date 03.05.2023 Revision: 03.05.2023 Version number 1.0

Trade name: Oxandrolone

(Contd. of page 6)

15 Regulatory information

- · Safety, health and environmental regulations/legislation specific for the substance or mixture
- · Australian Inventory of Industrial Chemicals Substance is not listed.
- · Standard for the Uniform Scheduling of Medicines and Poisons S4+APPENDIX D
- · Australia: Priority Existing Chemicals Substance is not listed.
- · Directive 2012/18/EU
- · Named dangerous substances ANNEX I Substance is not listed.
- · National regulations:
- · Information about limitation of use:

Workers are not allowed to be exposed to this hazardous material. Exceptions can be made by the authorities in certain cases.

- · Other regulations, limitations and prohibitive regulations
- Therapeutic goods are listed on the Australian Register of Therapeutic Goods(ARTG)
- · Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- · Department issuing SDS: Product Safety Department
- Contact:
- · Abbreviations and acronyms:

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement

Concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

EINECS: European Inventory of Existing Commercial Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Acute Tox. 4: Acute toxicity - Category 4

Resp. Sens. 1: Respiratory sensitisation - Category 1

Skin Sens. 1: Skin sensitisation - Category 1

Carc. 1B: Carcinogenicity – Category 1B

Repr. 1A: Reproductive toxicity - Category 1A

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