



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 : Medroxyprogesterone

Product code : 201600552

Synonyms : Medroxyprogesterone, salts, hydrates, isomers and impurities where applicable

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]

Reproductive toxicity, Category 1A

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) :



GHS08

Signal word (CLP) : Danger

Hazard statements (CLP) : H360 - May damage fertility or the unborn child.

Precautionary statements (CLP) : P202 - Do not handle until all safety precautions have been read and understood.

P308+P313 - IF exposed or concerned: Get medical advice/attention.

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

Hazard pictograms (CLP) :

H360

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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]
Medroxyprogesterone	-	≤ 100	Repr. 1A, H360

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/....

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.

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

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.

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.

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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.

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 containment 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 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 : Comply with applicable regulations.

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

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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

Particle size

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 Appearance : Powder. : Not applicable. Odour Odour threshold : Not available Melting point : Not available Freezing point : Not available : Not available Boiling point 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 : Not available Decomposition temperature : Not available pH solution : Not available Viscosity, kinematic : Not applicable Solubility : Water: < 0,1 g/l Partition coefficient n-octanol/water (Log Kow) : Not available Vapour pressure : Not available : Not available Vapour pressure at 50°C : Not available Density Relative density : Not available Relative vapour density at 20°C : Not applicable

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: Not available

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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) : Not classified
Acute toxicity (dermal) : Not classified
Acute toxicity (inhalation) : Not classified

Medroxyprogesterone

LD50 oral rat

Skin corrosion/irritation : Not classified (Lack of data)

Serious eye damage/irritation : Not classified (Lack of data)

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

> 2000 mg/kg

Germ cell mutagenicity : Not classified (Lack of data)

Carcinogenicity : Not classified (Conclusive but not sufficient for classification)

Medroxyprogesterone

IARC group 2B - Possibly carcinogenic to humans

Reproductive toxicity : May damage fertility or the unborn child.

STOT-single exposure : Not classified STOT-repeated exposure : Not classified

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

11.2. Information on other hazards

No additional information available

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SECTION 12: Ecological information

12.1. Toxicity

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

Hazardous to the aquatic environment, short-term : Not classified

(acute)

Hazardous to the aquatic environment, long-term : Not classified

(chronic)

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.

SECTION 14: Transport information

In accordance with ADR / IMDG / IATA

ADR	IMDG	IATA		
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		
No supplementary information available				

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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

Full text of H- and EUH-statements:	
H360	May damage fertility or the unborn child.
Repr. 1A	Reproductive toxicity, Category 1A

Safety Data Sheet (SDS), EU

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