

# Prednisolone acetate

## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878  
Issue date: 07/07/2025 Version: 1.0

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

#### 1.1. Product identifier

Product form : Substance  
Substance name : Prednisolone acetate  
Chemical name : Prednisolone acetate  
EC-No. : 200-134-1  
CAS-No. : 52-21-1  
Product code : 202500490

#### 1.2. Relevant identified uses of the substance or mixture and uses advised against

##### Relevant identified uses

Use of the substance/mixture : Scientific research and development  
Technical testing and analysis  
For professional use only  
Function or use category : Laboratory chemicals

##### Uses advised against

Restrictions on use : Not for food, drug or home use

#### 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](mailto:sds@edqm.eu), [www.edqm.eu](http://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]

Endocrine disruptor for the environment, Category 2 EUH431  
Endocrine disruptor for human health, Category 1 EUH380  
Reproductive toxicity, Category 1B H360  
Specific target organ toxicity – Repeated exposure, Category 1 H372  
Full text of H- and EUH-statements: see section 16

##### Adverse physicochemical, human health and environmental effects

May damage fertility or the unborn child. Causes damage to organs through prolonged or repeated exposure.

#### 2.2. Label elements

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

Hazard pictograms (CLP) :



GHS08

Signal word (CLP) : Danger  
Hazard statements (CLP) : EUH380 - May cause endocrine disruption in humans.  
EUH431 - Suspected of causing endocrine disruption in the environment.

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### Precautionary statements (CLP)

- H360 - May damage fertility or the unborn child.  
H372 - Causes damage to organs (cardiovascular system, endocrine system, nervous system, kidneys, skeleton, skin, eyes) through prolonged or repeated exposure.
- : 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.  
P314 - Get medical advice/attention if you feel unwell.  
P391 - Collect spillage.  
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)



GHS08

### 2.3. Other hazards

The substance is included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is 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

### Other information

- : Active substance (in pharmaceutical products).  
Warning - substance not yet tested completely.

## SECTION 3: Composition/information on ingredients

### 3.1. Substances

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Prednisolone acetate substance identified as having endocrine disrupting properties	CAS-No.: 52-21-1 EC-No.: 200-134-1	≤ 100	ED ENV 2, EUH431 ED HH 1, EUH380 Repr. 1B, H360 STOT RE 1, H372

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 general : In all cases of doubt, or when symptoms persist, seek medical attention.
- First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing. Allow the victim to rest. If the person feels unwell : Get medical advice/attention.
- First-aid measures after skin contact : Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.
- First-aid measures after eye contact : Rinse with water while holding the eyes wide open. Obtain medical attention if pain, blinking or redness persists.
- First-aid measures after ingestion : Rinse mouth out with water (only if the person is conscious). Never give anything by mouth to an unconscious person. Get immediate medical advice/attention.

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

No additional information available

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

No additional information available

## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

- |                                |   |
|--------------------------------|---|
| Suitable extinguishing media   | : Use extinguishing media appropriate for surrounding fire. Carbon dioxide. Water spray. Dry powder. Extinguishing blanket. |
| Unsuitable extinguishing media | : Do not use a heavy water stream.  |

### 5.2. Special hazards arising from the substance or mixture

- |  |  |
|--|--|
| Hazardous decomposition products in case of fire | : Incomplete combustion releases dangerous carbon monoxide, carbon dioxide and other toxic gases. Toxic fumes may be released. |
|--|--|

### 5.3. Advice for firefighters

- |                                |  |
|--------------------------------|--|
| Firefighting instructions      | : Prevent fire fighting water from entering the environment.   |
| Protection during firefighting | : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing. |

## SECTION 6: Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

- |                                    |   |
|------------------------------------|---|
| General measures                   | : Avoid contact with skin, eyes and clothing.   |
| <b>For non-emergency personnel</b> |   |
| Emergency procedures               | : Evacuate unnecessary personnel.   |
| <b>For emergency responders</b>    |   |
| Protective equipment               | : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection". |

### 6.2. Environmental precautions

Avoid release to the environment. Prevent entry to sewers and public waters.

### 6.3. Methods and material for containment and cleaning up

- |                         |   |
|-------------------------|---|
| For containment         | : Absorb with an inert material and place in an appropriate waste disposal container.     |
| Methods for cleaning up | : Clean contaminated surfaces with an excess of water. Clean with the help of detergents. |

### 6.4. Reference to other sections

See Section 13 for disposal information.

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

- |                                   |  |
|-----------------------------------|--|
| Additional hazards when processed | : Do not expose pregnant or breastfeeding women.   |
| Precautions for safe handling     | : Avoid all unnecessary exposure. Ensure good ventilation of the work station.   |
| Hygiene measures                  | : Do not eat, drink or smoke when using this product. Contaminated work clothing should not be allowed out of the workplace. Wash hands before work breaks and after finishing work. |

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### 7.2. Conditions for safe storage, including any incompatibilities

Storage conditions	: Store in a well-ventilated place. Keep container tightly closed. Keep away from heat and direct sunlight.
Packaging materials	: Keep in original containers.

### 7.3. Specific end use(s)

No additional information available

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

No additional information available

### 8.2. Exposure controls

#### Appropriate engineering controls

##### Appropriate engineering controls:

Ensure good ventilation of the work station. Both local exhaust and general room ventilation are usually required. Material should be handled in a laboratory hood whenever possible.

#### Personal protection equipment

##### Eye and face protection

##### Eye protection:

Wear eye protection. Safety glasses with side shields. (EN 166)

##### Skin protection

##### Skin and body protection:

Wear suitable protective clothing. Laboratory use : Lab coat. (EN 13034)

##### Hand protection:

Wear suitable gloves. Chemically resistant protective gloves. (EN 374)

##### Respiratory protection

##### Respiratory protection:

In case of dust formation use respirator with filter: P3

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

Physical state	: Solid
Colour	: white. almost white.
Appearance	: Crystalline powder.
Molecular mass	: 402.5 g/mol
Odour	: Not available
Odour threshold	: Not available
Melting point	: > 235 °C (decomposition)
Freezing point	: Not available
Boiling point	: Not available
Flammability	: Not available
Lower explosion limit	: Not applicable
Upper explosion limit	: Not applicable
Flash point	: Not applicable
Auto-ignition temperature	: Not applicable
Decomposition temperature	: Not available
pH	: Not available
pH solution	: Not available
Viscosity, kinematic	: Not applicable
Solubility	: Water: < 0.1 g/l

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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

No additional information available

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

No additional information available

### 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

No additional information available

### 10.6. Hazardous decomposition products

No additional information available

## SECTION 11: Toxicological information

### 11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral)	: Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (dermal)	: Not classified (Lack of data)
Acute toxicity (inhalation)	: Not classified (Lack of data)

Prednisolone acetate (52-21-1)	
LD50 oral rat	> 2000 mg/kg (estimated value)
Skin corrosion/irritation	: Not classified (Based on available data, the classification criteria are not met)
Serious eye damage/irritation	: Not classified (Based on available data, the classification criteria are not met)
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	: May damage fertility or the unborn child.
STOT-single exposure	: Not classified (Lack of data)
STOT-repeated exposure	: Causes damage to organs (cardiovascular system, endocrine system, nervous system, kidneys, skeleton, skin, eyes) through prolonged or repeated exposure.
Aspiration hazard	: Not classified (Lack of data)

### 11.2. Information on other hazards

#### Endocrine disrupting properties

Adverse health effects caused by endocrine disrupting properties	: Has an endocrine mode of action, i.e. it alters the function(s) of the endocrine system
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### SECTION 12: Ecological information

#### 12.1. Toxicity

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)

#### 12.2. Persistence and degradability

##### Prednisolone acetate (52-21-1)

Persistence and degradability	Rapidly degradable
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#### 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

Adverse effects on the environment caused by endocrine disrupting properties : Has an endocrine mode of action, i.e. it alters the function(s) of the endocrine system.

#### 12.7. Other adverse effects

No additional information available

### SECTION 13: Disposal considerations

#### 13.1. Waste treatment methods

No additional information available

### SECTION 14: Transport information

In accordance with ADR / IMDG / IATA

ADR	IMDG	IATA
<b>14.1. UN number or ID number</b>		
Not regulated for transport		
<b>14.2. UN proper shipping name</b>		
Not regulated	Not regulated	Not regulated
<b>14.3. Transport hazard class(es)</b>		
Not regulated	Not regulated	Not regulated
<b>14.4. Packing group</b>		
Not regulated	Not regulated	Not regulated
<b>14.5. Environmental hazards</b>		
Not regulated	Not regulated	Not regulated
No supplementary information available		

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### 14.6. Special precautions for user

#### Overland transport

Not regulated

#### Transport by sea

Not regulated

#### Air transport

Not regulated

### 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

#### 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

##### Ozone Regulation (1005/2009)

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

##### Council Regulation (EC) for the control of dual-use items

Not listed on the COUNCIL REGULATION (EC) of dual-use items.

##### Explosives Precursors Regulation (EU 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 (EC 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)

### 15.2. Chemical safety assessment

No additional information available

## SECTION 16: Other information

### Full text of H- and EUH-statements:

ED ENV 2	Endocrine disruptor for the environment, Category 2
ED HH 1	Endocrine disruptor for human health, Category 1
EUH380	May cause endocrine disruption in humans.
EUH431	Suspected of causing endocrine disruption in the environment.
H360	May damage fertility or the unborn child.
H372	Causes damage to organs (cardiovascular system, endocrine system, nervous system, kidneys, skeleton, skin, eyes) through prolonged or repeated exposure.
Repr. 1B	Reproductive toxicity, Category 1B

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### Full text of H- and EUH-statements:

STOT RE 1	Specific target organ toxicity – Repeated exposure, Category 1
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Safety Data Sheet (SDS), EU

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