Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 13.03.2023 Version number 1.00 Revision: 13.03.2023

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

· **Product identifier**

· **Trade name:** **Prednisolone acetate, micronized, API**

· **Article number:** 2551
· **CAS Number:**
52-21-1
· **EC number:**
200-134-1
· **Registration number** The substance is exempt from REACH-registration.
· **Relevant identified uses of the substance or mixture and uses advised against**
· **Application of the substance / the mixture**
Ingredient for pharmaceutical drugs or active pharmaceutical ingredient.
· **Uses advised against** No relevant information available.

· **Details of the supplier of the safety data sheet**
· **Manufacturer/Supplier:**
CAELO
Caesar & Loretz GmbH
Herderstr. 31
D-40721 Hilden
GERMANY

· **Further information obtainable from:**
E-mail: info@caelo.de
Tel.: +49210349940 (during regular opening hours)
· **Emergency telephone number:**
Poison Information Center Bonn
Venusberg-Campus 1, 53127 Bonn
Tel: +49 (0) 228-192400

2 Hazards identification

· **Classification of the substance or mixture**
· **Classification according to Regulation (EC) No 1272/2008**
Repr. 1A H360 May damage fertility or the unborn child.
STOT RE 2 H373 May cause damage to organs through prolonged or repeated exposure.

· **Label elements**
· **Labelling according to Regulation (EC) No 1272/2008**
The substance is classified and labelled according to the CLP regulation.
· **Hazard pictograms**

GHS08

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· **Signal word** Danger
· **Hazard statements**
H360 May damage fertility or the unborn child.
H373 May cause damage to organs through prolonged or repeated exposure.
· **Precautionary statements**
P260 Do not breathe dust/fume/gas/mist/vapours/spray.
P280 Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.
P308+P313 IF exposed or concerned: Get medical advice/attention.
P314 Get medical advice/attention if you feel unwell.
P405 Store locked up.
P501 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.
· **Determination of endocrine-disrupting properties** Not applicable.

3 Composition/information on ingredients

· **Substances**
· **CAS No. Description**
CAS: 52-21-1 Prednisolone 21-acetate
· **Identification number(s)**
· **EC number:** 200-134-1

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:** Bring the person out of the contaminated area to fresh air.
· **After skin contact:** Generally the product does not irritate the skin.
· **After eye contact:** Rinse opened eye for several minutes under running water.
· **After swallowing:**
Rinse out mouth and then drink plenty of water.
Call a doctor immediately.
· **Most important symptoms and effects, both acute and delayed**
No further relevant information available.
· **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

5 Firefighting measures

· **Extinguishing media**
· **Suitable extinguishing agents:**
All regular extinguishing media can be used.
Use fire extinguishing methods suitable to surrounding conditions.

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· **Special hazards arising from the substance or mixture** No further relevant information available.
· **Advice for firefighters**
· **Protective equipment:** In case of fire wear suitable protective clothes and respiratory protection.
· **Additional information**
Prevent from entering into drains. Fire residues must be disposed in accordance with official regulations.

6 Accidental release measures

· **Personal precautions, protective equipment and emergency procedures**
Avoid formation of dust.
Avoid contact with the substance.
Ensure adequate ventilation
· **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
· **Methods and material for containment and cleaning up:**
Take up dry. Clean up with water.
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

· **Precautions for safe handling**
Prevent formation of aerosols.
Prevent formation of dust.
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:**
Tightly closed.
Store in a cool location.
2-8°C
· **Information about storage in one common storage facility:** Not required.
· **Further information about storage conditions:**
Protect from exposure to the light.
Keep away from heat sources.
· **Storage class:** TRHS 510: 6.1 C Combustible acutely toxic or chronic substances
· **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

· **Control parameters**
· **Ingredients with limit values that require monitoring at the workplace:** Not required.
· **Additional information:** The lists valid during the making were used as basis.

· **Exposure controls**
· **Appropriate engineering controls** No further data; see item 7.

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· **Individual protection measures, such as personal protective equipment**
· **General protective and hygienic measures:**
Keep away from foodstuffs, beverages and feed.
Wash hands before breaks and at the end of work.
Store protective clothing separately.
· **Respiratory protection:** Dust protection mask.
· **Hand protection** Protective gloves
· **Material of gloves**
The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation
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/face protection** Tightly sealed goggles
· **Body protection:** Protective work clothing

9 Physical and chemical properties

· **Information on basic physical and chemical properties**
· **General Information**

· **Physical state**	Solid
· **Colour:**	White
· **Odour:**	Odourless
· **Odour threshold:**	Not determined.
· **Melting point/freezing point:**	230 °C
· **Boiling point or initial boiling point and boiling range**	Undetermined.
· **Flammability**	Product is not flammable.
· **Lower and upper explosion limit**	
· **Lower:**	Not determined.
· **Upper:**	Not determined.
· **Flash point:**	Not applicable.
· **Decomposition temperature:**	Not determined.
· **pH**	7
· **Viscosity:**	
· **Kinematic viscosity**	Not applicable.
· **Dynamic:**	Not applicable.
· **Solubility**	
· **water:**	Not determined.
· **Partition coefficient n-octanol/water (log value)**	Not determined.
· **Vapour pressure:**	Not applicable.
· **Density and/or relative density**	
· **Density:**	Not determined.
· **Relative density**	Not determined.
· **Vapour density**	Not applicable.

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· **Particle characteristics**	Not determined
· **Other information**	
· **Appearance:**	
· **Form:**	Crystalline
· **Important information on protection of health and environment, and on safety.**	
· **Auto-ignition temperature:**	Not determined.
· **Explosive properties:**	Product does not present an explosion hazard.
· **Change in condition**	
· **Evaporation rate**	Not applicable.
· **Information with regard to physical hazard classes**	
· **Explosives**	Void Void
· **Flammable gases**	Void Void
· **Aerosols**	Void Void
· **Oxidising gases**	Void Void
· **Gases under pressure**	Void Void
· **Flammable liquids**	Void Void
· **Flammable solids**	Void Void
· **Self-reactive substances and mixtures**	Void Void
· **Pyrophoric liquids**	Void Void
· **Pyrophoric solids**	Void Void
· **Self-heating substances and mixtures**	Void Void
· **Substances and mixtures, which emit flammable gases in contact with water**	Void Void
· **Oxidising liquids**	Void Void
· **Oxidising solids**	Void Void
· **Organic peroxides**	Void Void
· **Corrosive to metals**	Void Void

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· **Desensitised explosives** Void
Void

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** No dangerous reactions known.
· **Conditions to avoid** High temperature.
· **Incompatible materials:**
Alkalis
Oxidizing agent
Acids
· **Hazardous decomposition products:**
Carbon dioxide
Carbon monoxide

11 Toxicological information

· **Information on hazard classes as defined in Regulation (EC) No 1272/2008**
· **Acute toxicity** Based on available data, the classification criteria are not met.
· **Skin corrosion/irritation**
Irritant.
Based on available data, the classification criteria are not met.
· **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
· **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
· **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
· **Carcinogenicity** Based on available data, the classification criteria are not met.
· **Reproductive toxicity** May damage fertility or the unborn child.
· **STOT-single exposure**
May cause a respiratory tract irritation.
Based on available data, the classification criteria are not met.
· **STOT-repeated exposure** May cause damage to organs through prolonged or repeated exposure.
· **Aspiration hazard** Based on available data, the classification criteria are not met.
· **Information on other hazards**
· **Endocrine disrupting properties**
On the basis of the available data, the substance does not meet the criteria for the identification of substances having properties of interference with the endocrine system, in accordance with Article 59, paragraph 1 of the REACH Regulation and the criteria established in the Delegated Regulation (EU) 2017 / 2100 of the Commission or in Commission Regulation (EU) 2018/605.

12 Ecological information

· **Toxicity**
· **Aquatic toxicity:** No further relevant information available.
· **Persistence and degradability** No further relevant information available.
· **Bioaccumulative potential** No further relevant information available.

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· **Mobility in soil** No further relevant information available.
· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.
· **Endocrine disrupting properties**
Based on the available data, the substance does not meet the criteria for the identification of substances with properties affecting the endocrine system according to Article 59(1) of the REACH Regulation and the criteria of the Commission Delegated Regulation (EU) 2017/2100 or in the Commission Regulation (EU) 2018/605.
The product does not contain substances with endocrine disrupting properties.
· **Other adverse effects**
· **Additional ecological information:**
· **General notes:**
Water hazard class 3 (German Regulation) (Self-assessment): extremely hazardous for water
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

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 local regulations.

14 Transport information

· **UN number or ID number**	Not subject to transport regulations.
· **ADR, IMDG, IATA**	not regulated
· **UN proper shipping name**	
· **IMDG, IATA**	not regulated
· **Transport hazard class(es)**	
· **ADR, ADN, IMDG, IATA**	
· **Class**	not regulated
· **Packing group**	
· **ADR, IMDG, IATA**	not regulated
· **Environmental hazards:**	Not applicable.
· **Special precautions for user**	Not applicable.
· **Maritime transport in bulk according to IMO instruments**	Not applicable.
· **UN "Model Regulation":**	not regulated

15 Regulatory information

· **Safety, health and environmental regulations/legislation specific for the substance or mixture**
· **LIST OF SUBSTANCES SUBJECT TO AUTHORISATION (ANNEX XIV)** Not listed
· **REGULATION (EC) No 1907/2006 ANNEX XVII** Not listed

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· **DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II**
Substance is not listed.

· **National regulations:**
· **Storage of hazardous substances in in nonstationary vessels (TRGS 510) (Germany)**
TRHS 510: 6.1 C Combustible acutely toxic or chronic substances
· **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

16 Other information

The information provided is based on our current level of knowledge. This MSDS has been compiled and is exclusively for this product intended.
· **Reasons for alterations** This version replaces all old versions.
· **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
GHS: Globally Harmonised System of Classification and Labelling of Chemicals
EINECS: European Inventory of Existing Commercial Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
MAL-Code: Måleteknisk Arbejdshygiejnisk Luftbehov (Regulation for the labeling concerning inhalation hazards, Denmark)
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
Repr. 1A: Reproductive toxicity – Category 1A
STOT RE 2: Specific target organ toxicity (repeated exposure) – Category 2