

Trade name: Prednisolonum micronis.

Substance number: 847400

Version: 1 / CH

Date revised: 24.05.2023

Replaces Version: - / CH

Print date: 24.05.23

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

1.1. Product identifier

Prednisolonum micronis.

Item No. 84740002

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

Use of the substance/preparation

Active pharmaceutical substance

1.3. Details of the supplier of the safety data sheet

Address/Manufacturer

Hänseler AG

Industriestrasse 35

9100 Herisau

Telephone no. 0041 (0)71 353 58 58

E-mail address of sdb@haenseler.ch

person responsible

for this SDS

1.4. Emergency telephone number

Switzerland :145 / Abroad +41 (0)44 251 51 51

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification (Regulation (EC) No. 1272/2008)

Classification (Regulation (EC) No. 1272/2008)

Repr. 1B

H360D

The product is classified and labelled in accordance with Regulation (EC) No 1272/2008

For explanation of abbreviations see section 16.

2.2. Label elements

Labelling according to regulation (EC) No 1272/2008

Hazard pictograms



Signal word

Danger

Hazard statements

H360D

May damage the unborn child.

Precautionary statements

P201

Obtain special instructions before use.

P280

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

P308+P313

IF exposed or concerned: Get medicinal advice/attention.

P405

Store locked up.

P501.3

Disposal in compliance with local and national regulations.

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Hazardous component(s) to be indicated on label (Regulation (EC) No. 1272/2008)

contains prednisolone

Supplemental information**Further supplemental information**

Restricted to professional users

Other information

Not for supply to the general public in Switzerland

2.3. Other hazards

The Substance does not meet PBT-criteria. This substance does not meet the vPvB-criteria. This substance does not have endocrine disrupting properties with respect to humans. This substance does not have endocrine disrupting properties with respect to non-target organisms.

SECTION 3: Composition/information on ingredients**Hazardous ingredients****prednisolone**

CAS No. 50-24-8

EINECS no. 200-021-7

Concentration \geq 83 %Classification (Regulation (EC) No. 1272/2008)
Repr. 1B H360D

ATE oral 1'680 mg/kg

SECTION 4: First aid measures**4.1. Description of first aid measures****After inhalation**

Remove the casualty into fresh air and keep him calm. Summon a doctor immediately.

After skin contact

Remove contaminated, soaked clothing immediately and dispose of safely. Wash off immediately with soap and water and rinse well.

After eye contact

Remove contact lenses, irrigate copiously with clean, fresh water, holding the eyelids apart for at least 10 minutes and seek immediate medical advice.

After ingestion

Do not induce vomiting. Summon a doctor immediately.

SECTION 5: Firefighting measures**5.1. Extinguishing media****Suitable extinguishing media**

Compatible with all usual extinguishing media. Extinguishing measures to suit surroundings

5.2. Special hazards arising from the substance or mixture

The product is combustible. In case of combustion evolution of dangerous gases possible.

5.3. Advice for firefighters**Special protective equipment for fire-fighting**

Use personal protective clothing. Use self-contained breathing apparatus.

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Other information

Collect contaminated fire-fighting water separately, must not be discharged into the drains. Fire residues must be disposed of in a proper manner.

SECTION 6: Accidental release measures**6.1. Personal precautions, protective equipment and emergency procedures**

Women of childbearing age should avoid the contact with the product.

6.2. Environmental precautions

Do not empty into drains, caverns and basements.

6.3. Methods and material for containment and cleaning up

To pick up dry. Clean up affected area. When picked up, treat material as prescribed under Section 13 "Disposal".

6.4. Reference to other sections

Information regarding Safe handling, see Section 7. Information regarding personal protective measures, see Section 8. Information regarding waste disposal, see Section 13.

SECTION 7: Handling and storage**7.1. Precautions for safe handling****Advice on safe handling**

Provide good ventilation of working area (local exhaust ventilation if necessary).

Advice on protection against fire and explosion

No special measures required.

7.2. Conditions for safe storage, including any incompatibilities**Recommended storage temperature**

Value	15	25	°C
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Requirements for storage rooms and vessels

Keep tightly closed in a dry and cool place.

Storage classes

Storage class according to TRGS 510	6.1D	Non-combustible substances of acute toxicity, category 3 / hazardous substances that are toxic or produce chronic effects
Storage category (Switzerland)	6.1	

SECTION 8: Exposure controls/personal protection**8.2. Exposure controls****General protective and hygiene measures**

Keep away from food-stuffs, beverages and feed-stocks. Wash hands before breaks and after work.

Respiratory protection

Dust mask

Hand protection

The glove material must be sufficient impermeable and resistant to the substance. Check the tightness before wear. Gloves should be well cleaned before being removed, then stored in a well ventilated location.

Hand protection must comply with EN 374.

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Eye protection

Tightly fitting safety glasses

Body protection

Impermeable protective clothing

SECTION 9: Physical and chemical properties**9.1. Information on basic physical and chemical properties**

Physical state	solid	
Colour	white	
Odour	odourless	
Melting point		
Value	246.9	°C
Flammability		
Not ignitable		
Flash point		
Value	°C	
Remarks	Not applicable	
Partition coefficient n-octanol/water (log value)		
pOW	0.20412	
Vapour pressure		
Remarks	Not applicable	
Density and/or relative density		
Value	1.1	g/cm ³

9.2. Other information

Solubility in water		
Value	0.272	g/l
Explosive properties		
evaluation	no	

SECTION 10: Stability and reactivity**10.1. Reactivity**

None known

10.2. Chemical stability

No decomposition if stored and applied as directed.

10.3. Possibility of hazardous reactions

No hazardous reactions known.

10.4. Conditions to avoid

No hazardous reactions known.

10.5. Incompatible materials

None known

10.6. Hazardous decomposition products

None known

SECTION 11: Toxicological information

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

Acute oral toxicity

ATE	1'680	mg/kg
Method	calculated value (Regulation (EC) No. 1272/2008)	

Acute oral toxicity (Components)

prednisolone

Species	mouse	
LD50	1680	mg/kg

Acute dermal toxicity (Components)

prednisolone

Remarks	Not documented.
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Acute inhalative toxicity (Components)

prednisolone

Remarks	Not documented.
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Skin corrosion/irritation (Components)

prednisolone

Remarks	Based on available data, the classification criteria are not met.
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Serious eye damage/irritation (Components)

prednisolone

Remarks	Based on available data, the classification criteria are not met.
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Sensitization (Components)

prednisolone

Remarks	Based on available data, the classification criteria are not met.
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Reproduction toxicity (Components)

prednisolone

evaluation	May damage the unborn child.
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Carcinogenicity (Components)

prednisolone

Remarks	Based on available data, the classification criteria are not met.
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Specific Target Organ Toxicity (STOT) (Components)

prednisolone

Remarks	Based on available data, the classification criteria are not met.
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11.2 Information on other hazards

Endocrine disrupting properties with respect to humans

This substance does not have endocrine disrupting properties with respect to humans.

SECTION 12: Ecological information

12.1. Toxicity

Fish toxicity (Components)

prednisolone

Species	golden orfe (Leuciscus idus)	
LC50	> 500	mg/l

Bacteria toxicity (Components)

prednisolone

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EC50 2000 mg/l

12.2. Persistence and degradability**Biodegradability (Components)****prednisolone**

evaluation not degradable

12.3. Bioaccumulative potential**Partition coefficient n-octanol/water (log value)**

pOW 0.20412

12.5. Results of PBT and vPvB assessment**Results of PBT and vPvB assessment**

The Substance does not meet PBT-criteria.

This substance does not meet the vPvB-criteria.

12.6 Endocrine disrupting properties**Endocrine disrupting properties with respect to the environment**

This substance does not have endocrine disrupting properties with respect to non-target organisms.

SECTION 13: Disposal considerations**13.1. Waste treatment methods****Disposal recommendations for the product**

Do not dispose of it with household waste.

Do not allow to enter drains or water courses.

Disposal in compliance with local and national regulations.

Disposal recommendations for packaging

Dispose of as unused product.

SECTION 14: Transport information

	Land transport ADR/RID	Marine transport IMDG/GGVSee	Air transport ICAO/IATA
14.1. UN number	The product does not constitute a hazardous substance in land transport.	The product does not constitute a hazardous substance in sea transport.	The product does not constitute a hazardous substance in air transport.

SECTION 15: Regulatory information**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture****Water Hazard Class (Germany)**

Water Hazard Class WGK 2

(Germany)

Remarks Derivation of WGK according to Annex 1 No. 5.2 AwSV

SECTION 16: Other information**Hazard statements listed in Chapter 3**

H360D May damage the unborn child.

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CLP categories listed in Chapter 3

Repr. 1B

Reproductive toxicity, Category 1B

Supplemental information

Relevant changes compared with the previous version of the safety data sheet are marked with: ***

This information is based on our present state of knowledge. However, it should not constitute a guarantee for any specific product properties and shall not establish a legally valid relationship.