



Trade name: Prednisoloni acetat micronis.

Substance number: 067392

Version: 1 / CH

Date revised: 02.07.12

Replaces Version: - / CH

Date of printing: 02.07.12

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

1.1. Product identifier

Prednisoloni acetat micronis.

Item-No. 06739200

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

Hänseler AG
Industriestrasse 35
9101 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

2. Hazards identification

2.1. Classification of the substance or mixture

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

Classification (Regulation (EC) No. 1272/2008)
Repr. 1A H360

2.2. Label elements

Labelling according to regulation (EC) No 1272/2008

Hazard pictograms



Signal Word

Danger

Hazard statements

H360 May damage fertility or the unborn child.

Precautionary statements

P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P281 Use personal protective equipment as required.
P308+P313 IF exposed or concerned: Get medicinal advice/attention.
P405 Store locked up.
P501.3 Disposal in compliance with local and national regulations.

Labelling in accordance with EC directives 1999/45/EC and 67/548/EEC

The product is classified and labelled in accordance with EC directives/the relevant national laws.



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Hazard symbols

Toxic

R phrases

- 61 May cause harm to the unborn child.
62 Possible risk of impaired fertility.

S phrases

- 25 Avoid contact with eyes.
36/37 Wear suitable protective clothing and gloves.
38 In case of insufficient ventilation, wear suitable respiratory equipment.
22 Do not breathe dust.

Hazardous component(s) to be indicated on label

contains prednisolone 21-acetate

Special labelling for certain preparations

"Restricted to professional users"

3. Composition/information on ingredients**Hazardous ingredients****prednisolone 21-acetate**

CAS No.	52-21-1			
EINECS no.	200-134-1			
Concentration		>=	50	%
Classification	T			
	R61			
	R62			

Classification (Regulation (EC) No. 1272/2008)
Repr. 1A H360

4. First aid measures**4.1. Description of first aid measures****General information**

Remove contaminated, soaked clothing immediately and dispose of safely.

After inhalation

Ensure supply of fresh air. Summon a doctor immediately.

After skin contact

In case of contact with skin wash off immediately with plenty of water.

After eye contact

Separate eyelids, wash the eyes thoroughly with water (15 min.). Begin with medical treatment.

After ingestion

Summon a doctor immediately.

5. Firefighting measures



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5.1. Extinguishing media

Suitable extinguishing media

Carbon dioxide, Dry powder, Water spray jet, Foam, Sand

Non Suitable extinguishing media

Full water jet

5.2. Special hazards arising from the substance or mixture

If a fire breaks out nearby evolution of dangerous gases possible. In the event of fire the following can be released: Carbon monoxide (CO)

5.3. Advice for firefighters

Special protective equipment for fire-fighting

Use self-contained breathing apparatus. Wear full protective suit.

6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Wear protective equipment. Keep away unprotected persons. Ensure adequate ventilation.

6.2. Environmental precautions

Do not discharge into the drains/surface waters/groundwater.

6.3. Methods and material for containment and cleaning up

Pick up mechanically. Dispose of absorbed material in accordance with the regulations. Ensure adequate ventilation.

6.4. Reference to other sections

Information regarding Safe handling, see chapter 7. Information regarding personal protective measures see, chapter 8. Information regarding Waste Disposal, see chapter 13.

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). Avoid dust formation.

Advice on protection against fire and explosion

Keep away from sources of ignition - refrain from smoking. Dust can form an explosive mixture with air.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

No special requirements.

Hints on storage assembly

Not required.

Further information on storage conditions

Keep container tightly closed, cool and dry. Protect from light.

8. Exposure controls/personal protection

8.2. Exposure controls

Exposure controls

See chapter 7. No measures exceeding the ones mentioned are necessary.



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General protective and hygiene measures

Observe the usual precautions when handling chemicals. Remove contaminated, soaked clothing immediately and dispose of safely. Wash hands and face before breaks and after work. Wash thoroughly after work. It is essential for pregnant women to avoid inhaling the product and not to let it come in contact with the skin.

Respiratory protection

Short term: filter apparatus; At intensive and longer exposition use self-contained breathing apparatus.
Short term: filter apparatus, Filter P3

Hand protection

Gloves
Appropriate Material nitrile rubber - NBR
Plastic gloves

Eye protection

Tightly fitting safety glasses

Body protection

Clothing as usual in the chemical industry.

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

Form	Powder
Colour	whitish
Odour	perceptible
Melting point	
Value	230 to 240 °C
Boiling point	
Remarks	Not determined
Flash point	
Remarks	Not applicable
Density	
Remarks	Not determined
Solubility in water	
Remarks	insoluble
Octanol/water partition coefficient (log Pow)	
log Pow	2.40
Thermal decomposition	
Remarks	No decomposition if used as prescribed.

10. Stability and reactivity**10.4. Conditions to avoid****Thermal decomposition**

Remarks No decomposition if used as prescribed.

10.5. Incompatible materials

Danger of dust explosion

10.6. Hazardous decomposition products

Carbon monoxide and carbon dioxide



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11. Toxicological information

11.1. Information on toxicological effects

Acute oral toxicity

Species	mouse	
LD50	> 500	mg/kg

Skin corrosion/irritation

Remarks	No effect of irritation known.
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Serious eye damage/irritation

Remarks	Irritates the eyes.
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Sensitization

Remarks	No sensitisation effect known.
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12. Ecological information

12.1. Toxicity

Fish toxicity

Remarks	No data available.
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12.3. Bioaccumulative potential

Octanol/water partition coefficient (log Pow)

log Pow	2.40
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12.6. Other adverse effects

General information / ecology

Product is hazardous to water. Do not allow it to reach ground water, water bodies or sewage system.

13. Disposal considerations

13.1. Waste treatment methods

Disposal recommendations for the product

In accordance with regulations for special waste, must be taken, to an underground disposal site.

Disposal recommendations for packaging

Disposal in compliance with local and national regulations.

14. Transport information

Land transport ADR/RID

Non-dangerous goods

Marine transport IMDG/GGVSee

The product does not constitute a hazardous substance in sea transport.

Air transport ICAO/IATA

The product does not constitute a hazardous substance in air transport.

15. Regulatory information

15.2. Chemical safety assessment

For this substance a chemical safety assessment has not been carried out.



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16. Other information

R-phrases listed in chapter 3

61 May cause harm to the unborn child.
62 Possible risk of impaired fertility.

Hazard statements listed in chapter 3

H360 May damage fertility or the unborn child.

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.