

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

- **Product identifier**
- **Trade name:** Hydrocortisone acetate micronised  
Hydrocortisoni acetas micronisatum
- **Article number:**  
157000  
100543
- **CAS Number:**  
50-03-3
- **EC number:**  
200-004-4
- **Relevant identified uses of the substance or mixture and uses advised against**  
No further relevant information available.
- **Application of the substance / the preparation** Pharma Active ingredients
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
Fagron UK Ltd  
First Floor, 1 Pink Lane  
Newcastle upon Tyne  
England NE1 5DW
- **Further information obtainable from:** Tel.: +44 (0) 845 652 2525
- **Emergency telephone number:**  
Emergency response telephone number:  
+44 (0) 845 652 2525

## 2 Hazards identification

- **Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**



GHS08 health hazard

Repr. 2 H361 Suspected of damaging fertility or the unborn child.

- **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**



Xn; Harmful

R63: Possible risk of harm to the unborn child.

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- **Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**  
The substance is classified and labelled according to the CLP regulation.
- **Hazard pictograms** GHS08
- **Signal word** Warning
- **Hazard statements**  
H361 Suspected of damaging fertility or the unborn child.
- **Precautionary statements**  
P281 Use personal protective equipment as required.  
P201 Obtain special instructions before use.  
P202 Do not handle until all safety precautions have been read and understood.  
P308+P313 IF exposed or concerned: Get medical advice/attention.

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P405 Store locked up.

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

· **Additional information:** Void

· **Other hazards**

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

## 3 Composition/information on ingredients

· **Chemical characterization: Substances** Formular: C23H32O6 Mr.: 404.5

· **CAS No. Description**

50-03-3 Hydrocortisone acetate micronised

Hydrocortisoni acetas micronisatum

· **Identification number(s)**

· **EC number:** 200-004-4

## 4 First aid measures

· **Description of first aid measures**

· **General information:**

Immediately remove any clothing soiled by the product.

In case of irregular breathing or respiratory arrest provide artificial respiration.

· **After inhalation:** Supply fresh air or oxygen; call for doctor.

· **After skin contact:**

Immediately wash with water and soap and rinse thoroughly.

Seek medical treatment.

· **After eye contact:** Rinse opened eye for several minutes under running water. Then consult a doctor.

· **After swallowing:**

Seek medical treatment.

Rinse mouth with water.

· **Information for doctor:**

· **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:**

Water spray

Carbon dioxide

Fire-extinguishing powder

Alcohol resistant foam

· **Special hazards arising from the substance or mixture**

In case of fire, the following can be released:

Carbon monoxide (CO)

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- **Advice for firefighters**
- **Protective equipment:** Wear self-contained respiratory protective device.

## 6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**  
Wear protective equipment. Keep unprotected persons away.  
Ensure adequate ventilation
- **Environmental precautions:** Do not allow product to reach sewage system or any water course.
- **Methods and material for containment and cleaning up:**  
Pick up mechanically.  
Dispose of the material collected according to regulations.
- **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

- **Handling:**
- **Precautions for safe handling**  
Ensure good ventilation/exhaustion at the workplace.  
Prevent formation of dust.  
Prevent formation of aerosols.
- **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:** No special requirements.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:**  
Store in cool, dry conditions in well sealed receptacles.  
Protect from exposure to the light.
- **Specific end use(s)** No further relevant information available.

## 8 Exposure controls/personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.
- **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**
- **Personal protective equipment:**
- **General protective and hygienic measures:**  
The usual precautionary measures are to be adhered to when handling chemicals.  
Pregnant women should strictly avoid inhalation or skin contact.  
Immediately remove all soiled and contaminated clothing  
Be sure to clean skin thoroughly after work and before breaks.

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• **Respiratory protection:**

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

Filter P3

• **Protection of hands:**



Protective gloves

• **Material of gloves**

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 protection:**



Tightly sealed goggles

• **Body protection:** Protective work clothing

## 9 Physical and chemical properties

• **Information on basic physical and chemical properties**

• **General Information**

• **Appearance:**

**Form:** Crystalline powder

**Colour:** White

• **Odour:** odourless

• **Change in condition**

**Melting point/Melting range:** 223 °C (Zersetzung)

**Boiling point/Boiling range:** Undetermined.

• **Flash point:** Not applicable.

• **Danger of explosion:** Not determined.

• **Density:** Not determined.

• **Solubility in / Miscibility with**

**water:** Insoluble.

• **Other information** No further relevant information available.

## 10 Stability and reactivity

• **Reactivity**

• **Chemical stability**

• **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.

• **Possibility of hazardous reactions** Reacts with strong oxidizing agents.

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- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** Carbon monoxide and carbon dioxide

## 11 Toxicological information

### · Information on toxicological effects

#### · Acute toxicity:

#### · LD/LC50 values relevant for classification:

Oral	LD50	> 5000 mg/kg (rat)
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#### · Primary irritant effect:

· **on the skin:** Irritant to skin and mucous membranes.

· **on the eye:** Irritating effect.

· **Sensitization:** No sensitizing effects known.

#### · Additional toxicological information:

The product can cause inheritable damage.

Product is suspected to cause damage to fertility.

#### · CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)

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## 12 Ecological information

### · Toxicity

· **Aquatic toxicity:** No further relevant information available.

· **Persistence and degradability** No further relevant information available.

#### · Behaviour in environmental systems:

· **Bioaccumulative potential** No further relevant information available.

· **Mobility in soil** No further relevant information available.

#### · Additional ecological information:

· **General notes:** Do not allow product to reach ground water, water course or sewage system.

#### · Results of PBT and vPvB assessment

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

· **Other adverse effects** No further relevant information available.

## 13 Disposal considerations

### · Waste treatment methods

· **Recommendation** Must be specially treated adhering to official regulations.

### · Uncleaned packaging:

· **Recommendation:** Disposal must be made according to official regulations.

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## 14 Transport information

· UN-Number	
· ADR, ADN, IMDG, IATA	Void
· UN proper shipping name	
· ADR, ADN, IMDG, IATA	Void
· Transport hazard class(es)	
· ADR, ADN, IMDG, IATA	
· Class	Void
· Packing group	
· ADR, IMDG, IATA	Void
· Special precautions for user	Not applicable.
· Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable.
· Transport/Additional information:	Not dangerous according to the above specifications.
· UN "Model Regulation":	-

## 15 Regulatory information

- **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

## 16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

### · Department issuing MSDS:

Fagron UK  
Quality Assurance

### · Contact: kathryn.mason@fagron.co.uk

### · Abbreviations and acronyms:

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)

ICAO: International Civil Aviation Organization

ADR: Accord européen sur le transport 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 Harmonized 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)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

### · \* Data compared to the previous version altered.

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