

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

Printing date 30.08.2021

Version number 1.00

Revision: 25.08.2021

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

- **Product identifier**
- **Trade name:** Betamethasone dipropionate, micronized, API
- **Article number:** 5082
- **CAS Number:**  
5593-20-4
- **EC number:**  
227-005-2
- **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. 2 H361 Suspected of damaging fertility or the unborn child.
- **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

(Contd. on page 2)



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

Printing date 30.08.2021

Version number 1.00

Revision: 25.08.2021

**Trade name: Betamethasone dipropionate, micronized, API**

(Contd. of page 1)

**· Hazard statements**

H361 Suspected of damaging 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.

P280 Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.

P308+P313 IF exposed or concerned: Get medical advice/attention.

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.

### 3 Composition/information on ingredients

**· Chemical characterisation: Substances****· CAS No. Description**

5593-20-4 Betamethasone dipropionate

**· Identification number(s)****· EC number:** 227-005-2

### 4 First aid measures

**· Description of first aid measures****· 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:** If symptoms persist consult doctor.**· 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:**

All regular extinguishing media can be used.

Use fire extinguishing methods suitable to surrounding conditions.

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

Formation of toxic gases is possible during heating or in case of fire.

**· Advice for firefighters****· Protective equipment:** In case of fire wear suitable protective clothes and respiratory protection.

(Contd. on page 3)



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

Printing date 30.08.2021

Version number 1.00

Revision: 25.08.2021

---

**Trade name: Betamethasone dipropionate, micronized, API**

---

(Contd. of page 2)

**· 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 contact with the substance.

**· 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

**· Handling:**

**· Precautions for safe handling** No special precautions are necessary if used correctly.

**· Information about fire - and explosion protection:** Protect against electrostatic charges.

**· Conditions for safe storage, including any incompatibilities****· Storage:****· Requirements to be met by storerooms and receptacles:**

Tightly closed. Store at a dry place. At room temperature (+15°C to +25°C).

**· Information about storage in one common storage facility:** Not required.

**· Further information about storage conditions:** Protect from exposure to the light.

**· Storage class:** TRHS 510: 11 Combustible solids

**· 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.

**· Exposure controls****· 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.

**· Respiratory protection:** Dust protection mask.

**· Protection of hands:** 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

(Contd. on page 4)



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

Printing date 30.08.2021

Version number 1.00

Revision: 25.08.2021

---

**Trade name: Betamethasone dipropionate, micronized, API**

---

(Contd. of page 3)

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:** Solid material**Colour:** White**· Odour:** Odourless**· Odour threshold:** Not determined.**· pH-value:** Not applicable.**· Change in condition****Melting point/freezing point:** Undetermined.**Initial boiling point and boiling range:** Undetermined.**· Flash point:** Not applicable.**· Flammability (solid, gas):** Product is not flammable.**· Decomposition temperature:** Not determined.**· Auto-ignition temperature:** Not determined.**· Explosive properties:** Product does not present an explosion hazard.**· Explosion limits:****Lower:** Not determined.**Upper:** Not determined.**· Vapour pressure:** Not applicable.**· Density:** Not determined.**· Relative density** Not determined.**· Vapour density** Not applicable.**· Evaporation rate** Not applicable.**· Solubility in / Miscibility with****water:** Not determined.**· Partition coefficient: n-octanol/water:** Not determined.**· Viscosity:****Dynamic:** Not applicable.**Kinematic:** Not applicable.

(Contd. on page 5)



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

Printing date 30.08.2021

Version number 1.00

Revision: 25.08.2021

---

**Trade name: Betamethasone dipropionate, micronized, API**

---

(Contd. of page 4)

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

---

### 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** No further relevant information available.
  - **Incompatible materials:** No further relevant information available.
  - **Hazardous decomposition products:** Fluorocarbons
- 

### 11 Toxicological information

- **Information on toxicological effects**
  - **Acute toxicity** Based on available data, the classification criteria are not met.
  - **Primary irritant effect:**
  - **Skin corrosion/irritation** 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.
  - **Additional toxicological information:**
  - **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
  - **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**  
Suspected of damaging fertility or the unborn child.
  - **STOT-single exposure** Based on available data, the classification criteria are not met.
  - **STOT-repeated exposure** Based on available data, the classification criteria are not met.
  - **Aspiration hazard** Based on available data, the classification criteria are not met.
- 

### 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:**  
Water hazard class 2 (German Regulation) (Self-assessment): hazardous for water  
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
  - **Results of PBT and vPvB assessment**
  - **PBT:** Not applicable.
  - **vPvB:** Not applicable.
- 

(Contd. on page 6)



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

Printing date 30.08.2021

Version number 1.00

Revision: 25.08.2021

**Trade name: Betamethasone dipropionate, micronized, API**

(Contd. of page 5)

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

### 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** Not subject to transport regulations.
- **ADR, IMDG, IATA** not regulated
- **UN proper shipping name**
- **ADR, 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.
- **Transport in bulk according to Annex II of Marpol and the IBC Code** Not applicable.

### 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
- **National regulations:**
- **Storage of hazardous substances in in nonstationary vessels (TRGS 510) (Germany)**  
TRHS 510: 11 Combustible solids
- **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)

(Contd. on page 7)



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

Printing date 30.08.2021

Version number 1.00

Revision: 25.08.2021

---

**Trade name: Betamethasone dipropionate, micronized, API**

---

(Contd. of page 6)

MAL-Code: Måleteknisk Arbejdshygjensk Luftbehov (Regulation for the labeling concerning inhalation hazards, Denmark)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Repr. 2: Reproductive toxicity – Category 2

---

GB