

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 15.01.2021

Version number 3.00

Revision: 15.01.2021

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

- **Product identifier**
- **Trade name:** Dexamethasone, micronized, API
- **Article number:** 2211
- **CAS Number:**
50-02-2
- **EC number:**
200-003-9
- **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 Mainz
Langenbeckstr. 1, 55131 Mainz, Germany
Tel.: +49 (0) 6131/19240

* 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

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· 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**

50-02-2 dexamethasone

· Identification number(s)**· EC number:** 200-003-9

4 First aid measures

· Description of first aid measures**· After inhalation:**

Take affected persons into fresh air and keep quiet.

Call a doctor immediately.

· After skin contact: If skin irritation continues, consult a doctor.**· 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.

· 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 No further relevant information available.**· Advice for firefighters****· Protective equipment:** In case of fire wear suitable protective clothes and respiratory protection.

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· 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: No special measures required.**· 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:** No special measures required.**· 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:** No further information**· 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

· 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**

Rubber gloves

Natural rubber, NR

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.

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· 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:** Powder**Colour:** White**· Odour:** Odourless**· Odour threshold:** Not determined.**· pH-value:** Not applicable.**· Change in condition****Melting point/freezing point:** 250–253 °C**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: Insoluble.**· Partition coefficient: n-octanol/water:** Not determined.**· Viscosity:** Not applicable.**Dynamic:**

Not applicable.

Kinematic:

Not applicable.

· Other information No further relevant information available.

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10 Stability and reactivity

- **Reactivity** No further relevant information available.
- **Chemical stability**
- **Thermal decomposition / conditions to be avoided:** To avoid thermal decomposition do not overheat.
- **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:** No dangerous decomposition products known.

* 11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity** Based on available data, the classification criteria are not met.
- **LD/LC50 values relevant for classification:**
 - Oral LD50 3,000 mg/kg (rat)
 - LD50 (i.p.) 54 mg/kg (rat)
- **Primary irritant effect:**
- **Skin corrosion/irritation** Slightly irritant.
- **Serious eye damage/irritation** Slight irritation.
- **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
- **Additional toxicological information:** May have some genotoxic effects.
- **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
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

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* 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	
· 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: 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 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 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 Arbejdshygienisk Luftbehov (Regulation for the labeling concerning inhalation hazards, Denmark)

LC50: Lethal concentration, 50 percent

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LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Repr. 2: Reproductive toxicity – Category 2

· * Data compared to the previous version altered.

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