Safety Data Sheet

Cat. # API-04

Dexamethasone [10mM]

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

1.1. Product identifier
Product form: Substance
Substance name: dexamethasone
EC-No.: 200-003-9
CAS-No.: 50-02-2
Product code: 115D
Type of product: Pharmaceutical, The data relate to the active substance, Pure substance
Formula: C22H29FO5
Synonyms:
Product group: Raw material
BIG No.: 16180

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

1.2.1. Relevant identified uses
Use of the substance/mixture: Pharmaceutical product: active ingredient
Veterinary medicine: active ingredient

1.2.2. Uses advised against
No additional information available

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture
Classification according to Regulation (EC) No. 1272/2008 [CLP]
Not classified

Adverse physicochemical, human health and environmental effects
To our knowledge, this product does not present any particular risk, provided it is handled in accordance with good occupational hygiene and safety practice.
2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]
No labelling applicable

2.3. Other hazards
No additional information available

SECTION 3: Composition/information on ingredients

3.1. Substances

<table>
<thead>
<tr>
<th>Name</th>
<th>Product identifier</th>
<th>%</th>
<th>Classification according to Regulation (EC) No. 1272/2008 [CLP]</th>
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<td>(CAS-No.) 50-02-2 (EC-No.) 200-003-9</td>
<td>100</td>
<td>Not classified</td>
</tr>
</tbody>
</table>

3.2. Mixtures
Not applicable

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general:

First-aid measures after inhalation:
- Remove the victim into fresh air. Respiratory problems: consult a doctor/medical service.

First-aid measures after skin contact:
- Rinse with water. Soap may be used. Take victim to a doctor if irritation persists.

First-aid measures after eye contact:
- Rinse with water. Do not apply neutralizing agents. Take victim to an ophthalmologist if irritation persists.

First-aid measures after ingestion:
- Rinse mouth with water. Call Poison Information Centre (www.big.be/antigif.htm). Consult a doctor/medical service if you feel unwell. Ingestion of large quantities: immediately to hospital. Take the container/vomit to the doctor/hospital.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms/effects:
- See patient information on package leaflet.

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media:

Unsuitable extinguishing media:
- No unsuitable extinguishing media known.

5.2. Special hazards arising from the substance or mixture

Fire hazard:
- DIRECT FIRE HAZARD: No data available on direct fire hazard. INDIRECT FIRE HAZARD: No data available on indirect fire hazard.

Explosion hazard:
- DIRECT EXPLOSION HAZARD: No data available on direct explosion hazard. INDIRECT EXPLOSION HAZARD: No data available on indirect explosion hazard.

Hazardous decomposition products in case of fire:
- Toxic fumes may be released.

5.3. Advice for firefighters

Precautionary measures fire:
- Exposure to fire/heat: keep upwind. Exposure to fire/heat: consider evacuation. Exposure to fire/heat: have neighbourhood close doors and windows.

Firefighting instructions:
- Dilute toxic gases with water spray.

Protection during firefighting:
- Heat/fire exposure: compressed air/oxygen apparatus.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Protective equipment:
- Gloves. Protective clothing.

Emergency procedures:
- Mark the danger area. No naked flames. Wash contaminated clothes.

6.1.2. For emergency responders

Protective equipment:
- Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

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### 6.2. Environmental precautions
Prevent spreading in sewers.

### 6.3. Methods and material for containment and cleaning up

**For containment**
- Contain released product. Dam up the solid spill.

**Methods for cleaning up**
- Scoop solid spill into closing containers. Carefully collect the spill/leftovers. Clean contaminated surfaces with an excess of water. Wash clothing and equipment after handling.

**Other information**
- Dispose of materials or solid residues at an authorized site.

### 6.4. Reference to other sections
For further information refer to section 13.

### SECTION 7: Handling and storage

#### 7.1. Precautions for safe handling

**Precautions for safe handling**
- Comply with the legal requirements. Clean contaminated clothing. Do not discharge the waste into the drain. Avoid raising dust. Keep away from naked flames/heat. Observe normal hygiene standards. Keep container tightly closed. Carry operations in the open/under local exhaust/ventilation or with respiratory protection.

**Hygiene measures**
- Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

#### 7.2. Conditions for safe storage, including any incompatibilities

**Storage conditions**
- Store in a well-ventilated place. Keep cool.

**Heat and ignition sources**
- KEEP SUBSTANCE AWAY FROM: heat sources.

**Information on mixed storage**
- KEEP SUBSTANCE AWAY FROM: oxidizing agents. (strong) acids.

**Storage area**
- Store in a dry area. Store in a dark area. Meet the legal requirements.

**Special rules on packaging**
- SPECIAL REQUIREMENTS: closing. opaque. correctly labelled. meet the legal requirements. Secure fragile packagings in solid containers.

**Packaging materials**
- SUITABLE MATERIAL: No data available. MATERIAL TO AVOID: No data available.

#### 7.3. Specific end use(s)
No additional information available

### SECTION 8: Exposure controls/personal protection

#### 8.1. Control parameters
No additional information available

#### 8.2. Exposure controls

**Appropriate engineering controls:**
- Ensure good ventilation of the work station.

**Materials for protective clothing:**
- GIVE EXCELLENT RESISTANCE: No data available. GIVE GOOD RESISTANCE: No data available. GIVE LESS RESISTANCE: No data available. GIVE POOR RESISTANCE: No data available

**Hand protection:**
- Gloves

**Eye protection:**
- Safety glasses. In case of dust production: protective goggles

**Skin and body protection:**
- Protective clothing

**Respiratory protection:**
- Dust production: dust mask with filter type P1

**Environmental exposure controls:**
- Avoid release to the environment.

### SECTION 9: Physical and chemical properties

#### 9.1. Information on basic physical and chemical properties

**Physical state**
- Solid

**Appearance**
- Crystalline solid. Crystalline powder. May be present in various forms.

**Molecular mass**
- 392.47 g/mol

**Colour**
- White.

**Odour**
- No data available on odour.
**Odour threshold:** No data available

**pH:** No data available

**Relative evaporation rate (butylacetate=1):** No data available

**Melting point:** 262 °C

**Freezing point:** Not applicable

**Boiling point:** No data available

**Flash point:** Not applicable

**Auto-ignition temperature:** Not applicable

**Decomposition temperature:** No data available

**Flammability (solid, gas):** Non flammable.

**Vapour pressure:** < 0.1 hPa (20 °C)

**Relative vapour density at 20 °C:** No data available

**Relative density:** Not applicable

**Solubility:** Insoluble in water. Soluble in ethanol. Soluble in acetone. Soluble in chloroform.

**Water:** 0.01 g/100ml (25 °C)

**log Pow:** 1.83 (Experimental value)

**Viscosity, kinematic:** No data available

**Viscosity, dynamic:** No data available

**Explosive properties:** No data available

**Oxidising properties:** No data available

**Explosive limits:** Not applicable

**9.2. Other information**

**VOC content:** 0 %

**SECTION 10: Stability and reactivity**

**10.1. Reactivity**

On burning: release of toxic and corrosive gases/vapours (hydrofluoric acid, carbon monoxide - carbon dioxide).

**10.2. Chemical stability**

Stable under normal conditions.

**10.3. Possibility of hazardous reactions**

No dangerous reactions known under normal conditions of use.

**10.4. Conditions to avoid**

None under recommended storage and handling conditions (see section 7).

**10.5. Incompatible materials**

No additional information available

**10.6. Hazardous decomposition products**

Hazardous decomposition products.

**SECTION 11: Toxicological information**

**11.1. Information on toxicological effects**

**Acute toxicity (oral):** Not classified

**Acute toxicity (dermal):** Not classified

**Acute toxicity (inhalation):** Not classified

**Dexamethasone (50-02-2)**

**LD50 oral rat:** > 3000 mg/kg (Rat)

**Skin corrosion/irritation:** Not classified

**Serious eye damage/irritation:** Not classified

**Respiratory or skin sensitisation:** Not classified

**Germ cell mutagenicity:** Not classified

**Carcinogenicity:** Not classified

**Reproductive toxicity:** Not classified

**STOT-single exposure:** Not classified

**STOT-repeated exposure:** Not classified

**Aspiration hazard:** Not classified
### SECTION 12: Ecological information

#### 12.1. Toxicity

**Ecology - general:** The product is not considered harmful to aquatic organisms nor to cause long-term adverse effects in the environment.

**Ecology - air:** Not classified as dangerous for the ozone layer (Regulation (EC) No 1005/2009). TA-Luft Klasse 5.2.1.

**Ecology - water:** Mild water pollutant (surface water). Maximum concentration in drinking water: 1.5 mg/l (fluoride) (Directive 98/83/EC). No data available on ecotoxicity.

**Acute aquatic toxicity:** Not classified

**Chronic aquatic toxicity:** Not classified

#### 12.2. Persistence and degradability

**dexamethasone (50-02-2)**

Persistence and degradability: Biodegradability in water: no data available.

#### 12.3. Bioaccumulative potential

**dexamethasone (50-02-2)**

**Log Pow:** 1.83 (Experimental value)

**Bioaccumulative potential:** Low potential for bioaccumulation (Log Kow < 4).

#### 12.4. Mobility in soil

No additional information available

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

No additional information available

#### 12.6. Other adverse effects

No additional information available

### SECTION 13: Disposal considerations

#### 13.1. Waste treatment methods


**Product/Packaging disposal recommendations:** Remove waste in accordance with local and/or national regulations. Hazardous waste shall not be mixed together with other waste. Different types of hazardous waste shall not be mixed together if this may entail a risk of pollution or create problems for the further management of the waste. Hazardous waste shall be managed responsibly. All entities that store, transport or handle hazardous waste shall take the necessary measures to prevent risks of pollution or damage to people or animals. Dissolve or mix with a combustible solvent. Remove to an authorized incinerator equipped with an afterburner and a flue gas scrubber with energy recovery. Do not discharge into the sewer.

**Additional information:** LWCA (the Netherlands): KGA category 04. Hazardous waste according to Directive 2008/98/EC.

**European List of Waste (LoW) code:** 07 05 13* - solid wastes containing dangerous substances

### SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

#### 14.1. UN number

| UN-No. (ADR) | Not applicable |
| UN-No. (IMDG) | Not applicable |
| UN-No. (IATA) | Not applicable |
| UN-No. (ADN) | Not applicable |
| UN-No. (RID) | Not applicable |

#### 14.2. UN proper shipping name

| Proper Shipping Name (ADR) | Not applicable |
| Proper Shipping Name (IMDG) | Not applicable |
| Proper Shipping Name (IATA) | Not applicable |
| Proper Shipping Name (ADN) | Not applicable |
| Proper Shipping Name (RID) | Not applicable |

#### 14.3. Transport hazard class(es)

| ADR | Not applicable |
| IMDG | Not applicable |
dexamethasone
Safety Data Sheet
according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

IATA
Transport hazard class(es) (IATA) : Not applicable

ADN
Transport hazard class(es) (ADN) : Not applicable

RID
Transport hazard class(es) (RID) : Not applicable

14.4. Packing group
Packing group (ADR) : Not applicable
Packing group (IMDG) : Not applicable
Packing group (IATA) : Not applicable
Packing group (ADN) : Not applicable
Packing group (RID) : Not applicable

14.5. Environmental hazards
Dangerous for the environment : No
Marine pollutant : No
Other information : No supplementary information available

14.6. Special precautions for user
Overland transport
Transport regulations (ADR) : Not subject
Transport by sea
Transport regulations (IMDG) : Not subject
Air transport
Transport regulations (IATA) : Not subject
Inland waterway transport
No data available
Rail transport
Transport regulations (RID) : Not subject

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code
Not applicable

SECTION 15: Regulatory information
15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

15.1.1. EU-Regulations
No REACH Annex XVII restrictions
dexamethasone is not on the REACH Candidate List
dexamethasone is not on the REACH Annex XIV List
dexamethasone is not subject to REGULATION (EU) No 649/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 4 July 2012 concerning the export and import of hazardous chemicals.

VOC content : 0 %

15.1.2. National regulations
Not listed on the United States TSCA (Toxic Substances Control Act) inventory

15.2. Chemical safety assessment
No chemical safety assessment has been carried out

SECTION 16: Other information
Safety Data Sheet applicable for regions : GB - United Kingdom

SDS EU (REACH Annex II)
This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.