

## Safety Data Sheet

according to Regulation (EC) No 1907/2006 (REACH)  
Classifications according to Regulation (EC) No 1272/2008.  
Printdate 07 Feb 2023

## 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

### 1.1. Product name:

Budesonide

### 1.1. Catalog No.:

674581

### 1.2. Relevant identified uses of the substance or mixture

Identified: Laboratory chemical  
uses: R&D

### 1.3. Uses advised against:

HPC Standards GmbH  
Am Wieseneck 7

04451 Cunnersdorf  
Deutschland

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Fax. +49 34291 3372-39  
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### 1.4. Emergency telephone number

HPC Standards Tel. +49 34291 3372-36  
This number is only available during office hours.

## 2. HAZARDS IDENTIFICATION

· 2.1 Classification of the substance or mixture  
· Classification according to Regulation (EC) No 1272/2008  
GHS08 health hazard  
STOT RE 2 H373 May cause damage to organs through prolonged or repeated exposure.  
GHS07  
Skin Irrit. 2 H315 Causes skin irritation.  
Eye Irrit. 2 H319 Causes serious eye irritation.  
Skin Sens. 1 H317 May cause an allergic skin reaction.  
STOT SE 3 H335-H336 May cause respiratory irritation. May cause drowsiness or dizziness  
Lact. H362 May cause harm to breast-fed children.

### 2.2. Label elements

#### 2.2.1. Pictogram



## 2.2.2.

- 2.2 Label elements
- Labelling according to Regulation (EC) No 1272/2008  
The substance is classified and labelled according to the CLP regulation.
- Hazard pictograms  
GHS07 GHS08
- Signal word Warning
- Hazard statements  
H315 Causes skin irritation.  
H319 Causes serious eye irritation.  
H317 May cause an allergic skin reaction.  
H362 May cause harm to breast-fed children.  
H335-H336 May cause respiratory irritation. May cause drowsiness or dizziness.  
H373 May cause damage to organs through prolonged or repeated exposure.
- Precautionary statements  
P260 Do not breathe dusts or mists.  
P263 Avoid contact during pregnancy and while nursing.  
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
P321 Specific treatment (see on this label).  
P405 Store locked up.  
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.
- 2.3 Other hazards
- Results of PBT and vPvB assessment
- PBT: Not applicable.
- vPvB: Not applicable.

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

- 3.1 Chemical characterisation: Substances
- CAS No. Description  
51333-22-3 Budesonide
- Identification number(s) None
- EC number: 257-139-7
- RTECS: TU3723000
- Additional information: For the wording of the listed hazard phrases refer to section 16.

### 3.1.1. Formula

C25H34O6

### 3.1.2. Molecular Weight (g/mol)

430.53

### 3.1.3. CAS-No.

51333-22-3

## 4. FIRST AID MEASURES

- 4.1 Description of first aid measures
- General information:  
Symptoms of poisoning may occur even after several hours; therefore medical observation for at least 48 hours after the accident is recommended.
- After inhalation:  
Supply fresh air and call a doctor.  
In case of unconsciousness place patient in recovery position for transport.  
Seek medical treatment in case of complaints.  
Take affected persons into fresh air and keep quiet.
- After skin contact:  
Immediately wash with water and soap and rinse thoroughly.  
If skin irritation continues, consult a doctor.
- After eye contact:  
Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
- After swallowing: Rinse mouth. Do not induce vomiting.
- 4.2 Most important symptoms and effects, both acute and delayed No further relevant information available.
- 4.3 Indication of any immediate medical attention and special treatment needed  
No further relevant information available.

## 5. FIRE-FIGHTING MEASURES

- 5.1 Extinguishing media
- Suitable extinguishing agents: Use fire extinguishing methods suitable for surrounding conditions.
- 5.2 Special hazards arising from the substance or mixture  
Formation of toxic gases is possible during heating or in case of fire.
- 5.3 Advice for firefighters
- Protective equipment: Wear self-contained respiratory protective device.

## 6. ACCIDENTAL RELEASE MEASURES

- 6.1 Personal precautions, protective equipment and emergency procedures Wear protective clothing.
- 6.2 Environmental precautions: Do not allow to enter sewers/ surface or ground water.
- 6.3 Methods and material for containment and cleaning up:  
Dispose of contaminated material as waste according to item 13.
- 6.4 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

- 7.1 Precautions for safe handling Store in cool, dry place in tightly closed receptacles
- Information about fire - and explosion protection: No special measures required.
- 7.2 Conditions for safe storage, including any incompatibilities
- Storage:
  - Requirements to be met by storerooms and receptacles:  
Please refer to the manufacturers certificate for specific storage and transport temperature conditions.  
Store only in the original receptacle unless other advice is given on the CoA.  
Keep container in a well-ventilated place. Keep away from sources of ignition and heat.
- Information about storage in one common storage facility: Store away from foodstuffs.
- Further information about storage conditions: Keep container tightly sealed.
- 7.3 Specific end use(s) No further relevant information available.

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

- 8.1 Control parameters
  - Additional information about design of technical facilities: No further data; see item 7.
  - Ingredients with limit values that require monitoring at the workplace: Not required.
  - Additional information: Lists used were valid at the time of SDS preparation.
- 8.2 Exposure controls
  - Personal protective equipment:
    - General protective and hygienic measures:  
Keep away from foodstuffs, beverages and feed.  
Immediately remove all soiled and contaminated clothing  
Wash hands before breaks and at the end of work.  
Store protective clothing separately.  
Avoid contact with the eyes and skin.
  - 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.
  - Protection of hands:  
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  
The protective gloves to be used must comply with the specifications of EC Directive 89/686/EEC and the related standard EN374  
Protective gloves
    - Material of gloves Nitrile rubber, NBR
    - 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

## 9. PHYSICAL AND CHEMICAL PROPERTIES

- 9.1 Information on basic physical and chemical properties
  - General Information
  - Appearance:  
Form: Solid  
Colour: White
  - Odour: Odourless
  - Odour threshold: Not determined.
  - pH-value: Not applicable.
  - Change in condition  
Melting point/freezing point: Not determined.  
Not determined.  
Initial boiling point and boiling range: Not determined.
  - Flash point: Not applicable.
  - Flammability (solid, gas): Not determined.

- Ignition temperature: Not determined
- Decomposition temperature: Not determined.
- Auto-ignition temperature: Not determined.
- Explosive properties: Not determined.
- 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.
- 9.2 Other information No further relevant information available.

## 10. STABILITY AND REACTIVITY

- 10.1 Reactivity  
Stable under normal conditions.  
No further relevant information available.
- 10.2 Chemical stability Stable under normal conditions.
- Thermal decomposition / conditions to be avoided:  
Formation of toxic gases is possible during heating or in case of fire.
- 10.3 Possibility of hazardous reactions No dangerous reactions known.
- 10.4 Conditions to avoid Heat.
- 10.5 Incompatible materials: Strong oxidizing agents.
- 10.6 Hazardous decomposition products:  
Formation of toxic gases is possible during heating or in case of fire.

## 11. TOXICOLOGICAL INFORMATION

- 11.1 Information on toxicological effects
- Acute toxicity Based on available data, the classification criteria are not met.
- LD/LC50 values relevant for classification:  
Oral LD50 >3,200 mg/kg (rat)  
LD 50 (Intraperitoneal) 179 mg/kg (mouse)  
138 mg/kg (rat)  
LD 50 (Intravenous) 99 mg/kg (rat)
- Primary irritant effect:  
· Skin corrosion/irritation  
Causes skin irritation.
- Serious eye damage/irritation  
Causes serious eye irritation.
- Respiratory or skin sensitisation  
May cause an allergic skin reaction.
- Additional toxicological information:  
· CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)  
Lact.
- 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  
May cause harm to breast-fed children.
- STOT-single exposure  
May cause respiratory irritation. May cause drowsiness or dizziness.
- STOT-repeated exposure

May cause damage to organs through prolonged or repeated exposure.  
· Aspiration hazard Based on available data, the classification criteria are not met.

## 12. ECOLOGICAL INFORMATION

- 12.1 Toxicity
- Aquatic toxicity: No further relevant information available.
- 12.2 Persistence and degradability No further relevant information available.
- 12.3 Bioaccumulative potential No further relevant information available.
- 12.4 Mobility in soil No further relevant information available.
- Additional ecological information:
- General notes:  
Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water  
Do not allow undiluted product to reach ground water, water course or sewage system.
- 12.5 Results of PBT and vPvB assessment
- PBT: Not applicable.
- vPvB: Not applicable.
- 12.6 Other adverse effects No further relevant information available.

## 13. DISPOSAL CONSIDERATIONS

- 13.1 Waste treatment methods
- Recommendation  
Must not be disposed of together with household garbage. Do not allow product to reach sewage system.
- European waste catalogue  
Waste disposal key numbers from EWC have to be assigned depending on origin and processing.
- Uncleaned packaging:
- Recommendation: Dispose of in accordance with national regulations.

## 14. TRANSPORT INFORMATION

- 14.1 UN-Number
- ADR, IMDG, IATA Not applicable
- ADR, IMDG, IATA Not applicable
- 14.3 Transport hazard class(es)
- ADR, ADN, IMDG, IATA
- Class Not applicable
- 14.4 Packing group
- ADR, IMDG, IATA Not applicable
- 14.5 Environmental hazards: Not applicable.
- 14.6 Special precautions for user Not applicable.
- 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code Not applicable.
- UN "Model Regulation": Not applicable

## 15. REGULATORY INFORMATION

- 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
- Directive 2012/18/EU
- Named dangerous substances - ANNEX I Substance is not listed.
- DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment - Annex II Substance is not listed.
- 15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

## 16. OTHER INFORMATION

The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. For lab use only!