

according to Regulation (EC) No. 1907/2006 as amended by (EC) No. 1272/2008

Section 1. Identification of the Substance/Mixture and of the Company/Undertaking

- 1.1 Product Code:** 15407
Product Name: Budesonide
Synonyms: 16a,17-[butylidenebis(oxy)]-11 β ,21-dihydroxy-pregna-1,4-diene-3,20-dione; Entocort; Pulmicort
- 1.2 Relevant identified uses of the substance or mixture and uses advised against:**
Relevant identified uses: For research use only, not for human or veterinary use.
- 1.3 Details of the Supplier of the Safety Data Sheet:**
- Company Name:** Cayman Chemical Company
1180 E. Ellsworth Rd.
Ann Arbor, MI 48108
Web site address: www.caymanchem.com
Information: Cayman Chemical Company +1 (734)971-3335
- 1.4 Emergency telephone number:**
- Emergency Contact:** CHEMTREC Within USA and Canada: +1 (800)424-9300
CHEMTREC Outside USA and Canada: +1 (703)527-3887

Section 2. Hazards Identification

- 2.1 Classification of the Substance or Mixture:**
- 1.1 Classification according to Regulation (EC) No 1272/2008 [CLP]:**
Acute Toxicity: Inhalation, Category 4
Acute Toxicity: Skin, Category 4
Respiratory Sensitization, Category 1
Skin Sensitization, Category 1
Toxic To Reproduction, Category 2
- 2.1.2 Classification according to Directive 1999/45/EC:**
T: Toxic
Reproductive Hazard: 2
Risk Phrases: R20/21, R42, R43, R62, R63
For full text of R- phrases: see SECTION 15.
- 2.2 Label Elements:**
- 2.2.1 Labeling according to Regulation (EC) No 1272/2008 [CLP]:**



GHS Signal Word: Danger

GHS Hazard Phrases:

H332: Harmful if inhaled.

H312: Harmful in contact with skin.

H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.

H317: May cause an allergic skin reaction.

H361: Suspected of damaging fertility or the unborn child.

GHS Precaution Phrases:

- P261: Avoid breathing {dust/fume/gas/mist/vapours/spray}.
- P280: Wear {protective gloves/protective clothing/eye protection/face protection}.
- P362+364: Take off contaminated clothing and wash it before reuse.
- P284: {In case of inadequate ventilation, }wear respiratory protection {}.
- P272: Contaminated work clothing should not be allowed out of the workplace.
- P201: Obtain special instructions before use.
- P202: Do not handle until all safety precautions have been read and understood.
- P281: Use personal protective equipment as required.

GHS Response Phrases:

- P304+340: IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
- P312: Call a {POISON CENTER/doctor/...} if you feel unwell.
- P302+352: IF ON SKIN: Wash with plenty of soap and water.
- P321: Specific treatment {see ... on this label}.
- P304+341: IF INHALED: If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing.
- P342+311: If experiencing respiratory symptoms call a POISON CENTER or doctor/physician.
- P333+313: If skin irritation or rash occurs, seek medical advice/attention.
- P308+313: IF exposed or concerned: Get medical attention/advice.

GHS Storage and Disposal Phrases:

Please refer to Section 7 for Storage and Section 13 for Disposal information.

2.2.2 Labeling according to Directive 1999/45/EC:



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Reproductive Hazard: 2

2.3 Adverse Human Health

Harmful if inhaled.

Effects and Symptoms:

Harmful in contact with skin.

Material may be irritating to the mucous membranes and upper respiratory tract.

May be harmful by ingestion.

May cause allergy or asthma symptoms or breathing difficulties if inhaled.

May cause an allergic skin reaction.

May cause eye, skin, or respiratory system irritation.

Suspected of damaging fertility or the unborn child.

To the best of our knowledge, the toxicological properties have not been thoroughly investigated.

Section 3. Composition/Information on Ingredients

CAS # / RTECS #	Hazardous Components (Chemical Name)/ REACH Registration No.	Concentration	EC No./ EC Index No.	Risk Phrases/ GHS Classification
51333-22-3 TU3723000	Budesonide	100.0 %	257-139-7 NA	T; Rp:2, R20/21-42-43-62-63 Acute Tox.(D) 4: H312 Skin Sens. 1: H317 Acute Tox.(I) 4: H332 Resp. Sens. 1: H334 Toxic Repro. 2: H361

Section 4. First Aid Measures

Description of First Aid No data available.

Measures:

In Case of Inhalation: Remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Get immediate medical attention.

In Case of Skin Contact: Immediately wash skin with soap and plenty of water for at least 15 minutes. Remove contaminated clothing. Get medical attention if symptoms occur. Wash clothing before reuse.

In Case of Eye Contact: Hold eyelids apart and flush eyes with plenty of water for at least 15 minutes. Have eyes examined and tested by medical personnel.

In Case of Ingestion: Wash out mouth with water provided person is conscious. Never give anything by mouth to an unconscious person. Get medical attention. Do NOT induce vomiting unless directed to do so by medical personnel.

Section 5. Fire Fighting Measures

5.1 Suitable Extinguishing Use alcohol-resistant foam, carbon dioxide, water, or dry chemical spray.

Media: Use water spray to cool fire-exposed containers.

Unsuitable Extinguishing A solid water stream may be inefficient.

Media:

5.2 Flammable Properties and No data available.

Hazards:

Flash Pt: No data.

Explosive Limits: LEL: No data. UEL: No data.

Autoignition Pt: No data.

5.3 Fire Fighting Instructions: As in any fire, wear self-contained breathing apparatus pressure-demand (NIOSH approved or equivalent), and full protective gear to prevent contact with skin and eyes.

Section 6. Accidental Release Measures

6.1 Protective Precautions, Avoid raising and breathing dust, and provide adequate ventilation.

Protective Equipment and As conditions warrant, wear a NIOSH approved self-contained breathing apparatus, or respirator,
Emergency Procedures: and appropriate personal protection (rubber boots, safety goggles, and heavy rubber gloves).

6.2 Environmental Take steps to avoid release into the environment, if safe to do so.

Precautions:

6.3 Methods and Material For Contain spill and collect, as appropriate.

Containment and Cleaning Transfer to a chemical waste container for disposal in accordance with local regulations.

Up:

Section 7. Handling and Storage

7.1 Precautions To Be Taken Avoid breathing dust/fume/gas/mist/vapours/spray.

in Handling: Avoid prolonged or repeated exposure.

7.2 Precautions To Be Taken Keep container tightly closed.

in Storing: Store in accordance with information listed on the product insert.

Section 8. Exposure Controls/Personal Protection

8.1 Exposure Parameters:

CAS #	Partial Chemical Name	Britain EH40	France VL	Europe
51333-22-3	Budesonide	No data.	No data.	No data.



Budesonide

Revision: 10/16/2014

CAS #	Partial Chemical Name	OSHA TWA	ACGIH TWA	Other Limits
51333-22-3	Budesonide	No data.	No data.	No data.

8.2 Exposure Controls:

8.2.1 Engineering Controls Use process enclosures, local exhaust ventilation, or other engineering controls to control airborne (Ventilation etc.): levels below recommended exposure limits.

8.2.2 Personal protection equipment:

Eye Protection: Safety glasses

Protective Gloves: Compatible chemical-resistant gloves

Other Protective Clothing: Lab coat

Respiratory Equipment NIOSH approved respirator, as conditions warrant.

(Specify Type):

Work/Hygienic/Maintenance Practices: Do not take internally.

Facilities storing or utilizing this material should be equipped with an eyewash and a safety shower.

Wash thoroughly after handling.

No data available.

Section 9. Physical and Chemical Properties

9.1 Information on Basic Physical and Chemical Properties

Physical States: ☐ Gas ☐ Liquid ☒ Solid

Appearance and Odor: A crystalline solid

Melting Point: No data.

Boiling Point: No data.

Flash Pt: No data.

Evaporation Rate: No data.

Explosive Limits: LEL: No data. UEL: No data.

Vapor Pressure (vs. Air or mm Hg): No data.

Hg):

Vapor Density (vs. Air = 1): No data.

Specific Gravity (Water = 1): No data.

Solubility in Water: No data.

Solubility Notes: ~0.5 mg/ml in 1:1 DMSO:PBS (pH 7.2); ~10 mg/ml in EtOH; ~25 mg/ml in DMSO; ~20 mg/ml in DMF;

Autoignition Pt: No data.

9.2 Other Information

Percent Volatile: No data.

Molecular Formula & Weight: C₂₅H₃₄O₆ 430.5

Section 10. Stability and Reactivity

10.1 Reactivity: No data available.

10.2 Stability: Unstable ☐ Stable ☒

10.3 Stability Note(s): Stable if stored in accordance with information listed on the product insert.

Polymerization: Will occur ☐ Will not occur ☒

10.4 Conditions To Avoid: No data available.

10.5 Incompatibility - Materials strong oxidizing agents

To Avoid:

10.6 Hazardous carbon dioxide

Decomposition Or carbon monoxide



Budesonide

Revision: 10/16/2014

Byproducts:

Section 11. Toxicological Information

- 11.1 Information on Toxicological Effects:** The toxicological effects of this product have not been thoroughly studied.
Budesonide - Toxicity Data: Inhalation TCLO (human): 34 µg/kg; Oral LD50 (rat): >3200 mg/kg; Subcutaneous LD50 (rat): 58400 µg/kg; Oral LD50 (mouse): 4750 mg/kg; Subcutaneous LD50 (mouse): 53600 µg/kg;
- Chronic Toxicological Effects:** Budesonide - Investigated as a reproductive effector and tumorigen.
Only select Registry of Toxic Effects of Chemical Substances (RTECS) data is presented here.
See actual entry in RTECS for complete information.
Budesonide RTECS Number: TU3723000
- Carcinogenicity:** NTP? No IARC Monographs? No OSHA Regulated? No

Section 12. Ecological Information

- 12.1 Toxicity:** Avoid release into the environment.
Runoff from fire control or dilution water may cause pollution.
- 12.2 Persistence and Degradability:** No data available.
- 12.3 Bioaccumulative Potential:** No data available.
- 12.4 Mobility in Soil:** No data available.
- 12.5 Results of PBT and vPvB assessment:** No data available.

Section 13. Disposal Considerations

- 13.1 Waste Disposal Method:** Dispose in accordance with local, state, and federal regulations.

Section 14. Transport Information

14.1 LAND TRANSPORT (US DOT):

DOT Proper Shipping Name: Not dangerous goods.
DOT Hazard Class:
UN/NA Number:

14.1 LAND TRANSPORT (European ADR/RID):

ADR/RID Shipping Name: Not dangerous goods.
UN Number:
Hazard Class:

14.3 AIR TRANSPORT (ICAO/IATA):

ICAO/IATA Shipping Name: Not dangerous goods.

Additional Transport Information: Transport in accordance with local, state, and federal regulations.

Section 15. Regulatory Information

EPA SARA (Superfund Amendments and Reauthorization Act of 1986) Lists

AS #	Hazardous Components (Chemical Name)	S. 302 (EHS)	S. 304 RQ	S. 313 (TRI)
51333-22-3	Budesonide	No	No	No

CAS #	Hazardous Components (Chemical Name)	Other US EPA or State Lists
51333-22-3	Budesonide	CAA HAP, ODC: No; CWA NPDES: No; TSCA: No; CA PROP.65: No

European Community Hazard Symbol codes:



T

Reproductive Hazard: 2

European Community Risk and Safety Phrases:

R20/21	Harmful by inhalation and in contact with skin.
R42	May cause sensitization by inhalation.
R43	May cause sensitization by skin contact.
R62	Risk of impaired fertility.
R63	Possible risk of harm to the unborn child.
S24/25	Avoid contact with skin and eyes.
S36/37/39	Wear suitable protective clothing, gloves and eye/face protection.
S45	In case of accident or if you feel unwell, seek medical advice immediately (show the label whenever possible.)
S53	Avoid exposure - obtain special instructions before use.

Regulatory Information Statement: This SDS was prepared in accordance with Regulation (EC) No.1272/2008 and European Directive 67/548/EEC as amended.

Section 16. Other Information

Revision Date:	10/16/2014
Additional Information About This Product:	No data available.
Company Policy or Disclaimer:	DISCLAIMER: This information is believed to be accurate and represents the best information currently available to us. However, we make no warranty of merchantability or any other warranty, express or implied, with respect to such information, and we assume no liability resulting from its use. Users should make their own investigations to determine the suitability of the information for their particular purposes.