

## SAFETY DATA SHEET

Preparation Date: 8/2/2016

Revision Date: 8/2/2016

Revision Number: G1

### 1. IDENTIFICATION

**Product identifier**

**Product code:** B1595  
**Product Name:** BUDESONIDE, MICRONIZED, EP

**Other means of identification**

**Synonyms:** (11-beta,16-alpha)-16,17-(Butylidenebis(oxy))-11,21-dihydroxypregna-1,4-diene-3,20-dione;  
 16-alpha,17-alpha-Butylidenedioxy-11-beta,21-dihydroxy-1,4-pregnadiene-3,20-dione;  
 Pregna-1-4-diene-3,20-dione, 16.17-(butylidenebis(oxy))-11,21-dihydroxy-, (11-beta, 16-alpha)-  
 Pulmicort;  
 Bidien;  
 Budeson;  
 Rhinocort;  
 Budesonido;  
 Budesonidum

**CAS #:** 51333-22-3  
**RTECS #** TU3723000  
**CI#:** Not available

**Recommended use of the chemical and restrictions on use**

**Recommended use:** Drug. Hormone. Medication. In pharmaceuticals. Research and Development.  
**Uses advised against** No information available

**Supplier:** Spectrum Chemical Mfg. Corp  
 14422 South San Pedro St.  
 Gardena, CA 90248  
 (310) 516-8000.

**Order Online At:** <https://www.spectrumchemical.com>

**Emergency telephone number** Chemtrec 1-800-424-9300

**Contact Person:** Martin LaBenz (West Coast)

**Contact Person:** Ibad Tirmiz (East Coast)

### 2. HAZARDS IDENTIFICATION

**Classification**

This chemical is considered hazardous according to the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Not a dangerous substance or mixture according to the Globally Harmonized System (GHS)

Skin corrosion/irritation	Category 2
Serious eye damage/eye irritation	Category 2B
Reproductive toxicity	Category 2

**Label elements**

**Product code:** B1595

**Product name:** BUDESONIDE,  
MICRONIZED, EP

## Warning

### Hazard statements

Causes skin irritation  
Causes eye irritation  
Suspected of damaging fertility or the unborn child



### Hazards not otherwise classified (HNOC)

Not Applicable

### Other hazards

May be harmful if swallowed

### **Precautionary Statements - Prevention**

Obtain special instructions before use  
Do not handle until all safety precautions have been read and understood  
Wear protective gloves/protective clothing/eye protection/face protection  
Wash face, hands and any exposed skin thoroughly after handling

### **Precautionary Statements - Response**

*IF exposed or concerned: Get medical advice/attention*

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

IF ON SKIN: Wash with plenty of water

If skin irritation occurs: Get medical advice/attention

Take off contaminated clothing and wash it before reuse

### **Precautionary Statements - Storage**

Store locked up

### **Precautionary Statements - Disposal**

Dispose of contents/container to an approved waste disposal plant

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

Components	CAS-No.	Weight %
Budesonide	51333-22-3	100

## 4. FIRST AID MEASURES

### First aid measures

#### **General Advice:**

National Capital Poison Center in the United States can provide assistance if you have a poison emergency and need to talk to a poison specialist. Call 1-800-222-1222.

#### **Skin Contact:**

Wash off immediately with soap and plenty of water removing all contaminated clothing and shoes. Get medical attention. If skin irritation persists, call a physician.

#### **Eye Contact:**

Flush eyes with water for 15 minutes. Get medical attention. If symptoms persist, call a

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physician.

**Inhalation:** Move to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.

**Ingestion:** Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person. Obtain medical attention.

**Most important symptoms and effects, both acute and delayed**

**Symptoms** May cause nausea and vomiting. May cause heartburn. May cause headache. Somnolence. Analgesia. Muscle weakness. Glucocorticoids (Corticosteroids) may cause osteoporosis and bone fractures, back pain, joint pain/stiffness, numbness, weakness, infection, delayed wound healing, thinning skin, bruising, acne, menstrual irregularities, headache, sweating, eye pain, vision changes, mental and behavior changes, fever, muscle pain, immune system depression, purple lines on skin, tremors, Cushing's syndrome, electrolyte imbalance (sodium and fluid retention, potassium loss (hypokalemia). Contact causes skin irritation. Causes eye irritation.

**Indication of any immediate medical attention and special treatment needed**

**Notes to Physician:** Treat symptomatically.

**Protection of first-aiders**

First-Aid Providers: Avoid exposure to blood or body fluids. Wear gloves and other necessary protective clothing. Dispose of contaminated clothing and equipment as bio-hazardous waste.

**5. FIRE-FIGHTING MEASURES**

**Extinguishing Media**

**Suitable Extinguishing Media:** Dry chemical. Carbon dioxide (CO<sub>2</sub>). Water spray, mist, or foam.

**Unsuitable Extinguishing Media:** No information available.

**Specific hazards arising from the chemical**

**Hazardous Combustion Products:** Carbon oxides

**Specific hazards:** May be combustible at high temperatures

**Special Protective Actions for Firefighters**

**Specific Methods:** No information available.

**Special Protective Equipment for Firefighters:** As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear

## 6. ACCIDENTAL RELEASE MEASURES

### Personal precautions, protective equipment and emergency procedures

**Personal Precautions:** Ensure adequate ventilation. Keep people away from and upwind of spill/leak. Wear personal protective equipment. Avoid contact with skin, eyes and clothing. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Remove all sources of ignition.

**Environmental precautions** Prevent further leakage or spillage if safe to do so. Prevent entry into waterways, sewers, basements or confined areas. Prevent product from entering drains.

### Methods and material for containment and cleaning up

**Methods for containment** Stop leak if you can do it without risk. Cover with plastic sheet to prevent spreading.

**Methods for cleaning up** Sweep up and shovel into suitable containers for disposal. Clean contaminated surface thoroughly.

## 7. HANDLING AND STORAGE

### Precautions for safe handling

#### **Technical Measures/Precautions:**

Provide sufficient air exchange and/or exhaust in work rooms. Avoid dust formation. Keep away from incompatible materials.

#### **Safe Handling Advice**

Wear personal protective equipment. Avoid contact with skin, eyes and clothing. Do not ingest. Do not breathe dust. Keep away from heat and sources of ignition. Handle in accordance with good industrial hygiene and safety practice.

### Conditions for safe storage, including any incompatibilities

#### **Technical Measures/Storage Conditions:**

Keep container tightly closed in a dry and well-ventilated place. Store at room temperature in the original container. Store away from incompatible materials.

#### **Incompatible Materials:**

Oxidizing agents.

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Control parameters

#### **National occupational exposure limits**

##### **United States**

Components	CAS-No.	OSHA	NIOSH	ACGIH	AIHA WHEEL
Budesonide	51333-22-3	None	None	None	None

##### **Canada**

Components	CAS-No.	Canada - Alberta	Canada - British Columbia	Canada - Ontario	Canada - Quebec
Budesonide	51333-22-3	None	None	None	None

## Australia and Mexico

Components	CAS-No.	Australia	Mexico
Budesonide	51333-22-3	None	None

### Appropriate engineering controls

#### Engineering measures to reduce exposure:

Ensure adequate ventilation, especially in confined areas. Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

### Individual protection measures, such as personal protective equipment

#### Personal Protective Equipment

##### Eye protection:

Goggles or Safety glasses with side-shields

##### Skin and body protection:

Chemical resistant apron. Gloves. Long sleeved clothing.

##### Respiratory protection:

Effective dust mask. or. Wear respirator with dust filter. Be sure to use an approved/certified respirator or equivalent. Use a dust respirator under conditions where exposure to the substance is apparent (e.g. generation of high concentration of dust (dust clouds) , inadequate ventilation, development of respiratory tract irritation), and engineering controls are not feasible. Be sure to use an approved/certified respirator or equivalent.

##### Hygiene measures:

Avoid contact with skin, eyes and clothing. When using, do not eat, drink or smoke. Wash hands and face before breaks and immediately after handling the product.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

#### Physical state:

Solid

#### Appearance:

Powder.

#### Color:

White. Off-white.

#### Odor:

Odorless.

#### Taste

No information available.

#### Formula:

C25H34O6

#### Molecular/Formula weight:

430.59 g/mol

#### Flammability:

No information available

#### Flashpoint (°C/°F):

No information available.

#### Flash Point Tested according to:

Not available

#### Autoignition Temperature (°C/°F):

No information available

#### Lower Explosion Limit (%):

No information available

#### Upper Explosion Limit (%):

No information available

#### Melting point/range(°C/°F):

227°C/440°F

#### Decomposition temperature(°C/°F):

No information available

#### Boiling point/range(°C/°F):

No information available

#### Bulk density:

No information available

#### Density (g/cm3):

No information available

#### Specific gravity:

No information available

#### pH:

No information available

#### Vapor pressure @ 20°C (kPa):

No information available

**Evaporation rate:**  
No information available

**Vapor density:**  
No information available

**VOC content (g/L):**  
No information available

**Odor threshold (ppm):**  
No information available

**Partition coefficient  
(n-octanol/water):**  
1.6

**Viscosity:**  
No information available

**Miscibility:**  
No information available

**Solubility:**  
Insoluble in water  
Sparingly soluble in Ethyl alcohol  
Freely soluble in Chloroform

## 10. STABILITY AND REACTIVITY

### Reactivity

Reactive with oxidizing agents

### Chemical stability

**Stability:** Stable under recommended storage conditions.

**Possibility of Hazardous Reactions:** Hazardous polymerization does not occur

**Conditions to avoid:** Excess Heat. Avoid dust formation. Incompatible materials.

**Incompatible Materials:** Oxidizing agents.

**Hazardous decomposition products:** Carbon oxides.

### Other Information

**Corrosivity:** No information available

**Special Remarks on Corrosivity:** No information available

## 11. TOXICOLOGICAL INFORMATION

### Information on likely routes of exposure

**Principal Routes of Exposure:**  
Ingestion. Inhalation.

### Acute Toxicity

### Component Information

Budesonide

CAS-No. 51333-22-3

**LD50/oral/rat** = > 3200 mg/kg Oral LD50 Rat  
2435.9 mg/kg oral LD50 rat

**LD50/oral/mouse** = 4750 mg/kg oral LD50 mouse  
1700 mg/kg oral LD50 mouse

**LD50/dermal/rabbit** = No information available

**LD50/dermal/rat** = No information available

**LC50/inhalation/rat** = No information available

**LC50/inhalation/mouse** = No information available

**Other LD50 or LC50 information** = No information available

## Product Information

LD50/oral/rat =

VALUE- Acute Tox Oral = > 3200 mg/kg

LD50/oral/mouse =

Value - Acute Tox Oral = 4750 mg/kg

LD50/dermal/rabbit

VALUE-Acute Tox Dermal = No information available

LD50/dermal/rat

VALUE -Acute Tox Dermal = No information available

LC50/inhalation/rat

VALUE-Vapor = No information available

VALUE-Gas = No information available

VALUE-Dust/Mist = No information available

LC50/Inhalation/mouse

VALUE-Vapor = No information available

VALUE - Gas = No information available

VALUE - Dust/Mist = No information available

### Symptoms

**Skin Contact:** Causes skin irritation.

**Eye Contact:** Causes eye irritation.

**Inhalation** May cause irritation of respiratory tract.

**Ingestion** Corticosteroids(glucocorticoids): Nausea, vomiting, headache. May cause bone fractures, back pain, joint pain or stiffness, weakness, high blood pressure, increased appetite, infection, delayed wound healing, thinning skin, bruising, purple lines on skin, increased hair growth, acne, redistribution of body fat, menstrual irregularities, impotence, increased sweating, eye pain, vision changes, mental and personality changes, swelling, lightheadedness, numbness, tremors, Fluid and electrolyte imbalance (sodium and fluid retention), suppression of calcium absorption and increased calcium excretion, potassium loss, hypokalemic alkalosis, Cushing's syndrome, immune system depression. May cause heartburn.

**Aspiration hazard** No information available.

### Delayed and immediate effects as well as chronic effects from short and long-term exposure

**Chronic Toxicity** Prolonged or repeated ingestion of corticosteroids may cause osteoporosis and bone fractures due to mobilization of calcium (reduced calcium absorption) and phosphorus, hypokalemia due to increase urinary loss of potassium, development of glaucoma and cataracts, muscle weakness/muscle wasting, swelling of the feet or lower legs due fluid and sodium retention, hip or shoulder pain, irregular heartbeat. It may affect the liver, kidneys, pancreas (pancreatitis), blood (changes in serum composition), behavior/central nervous system (anxiety, nervousness or restlessness, trouble sleeping, mental disturbances such as psychosis, euphoria, depression), protein metabolism, lipid metabolism, carbohydrate metabolism causing insulin resistance, hyperglycemia, diabetes, and the immune system (immunosuppressant) causing increased susceptibility to infections), thinning skin. Repeated ingestion of large doses of corticosteroids may also produce other symptoms typical of hyperactivity of the adrenal gland and overproduction of

cortisol (Cushing's Syndrome) such moon-face, buffalo hump, increased bruising, ecchymoses, striae, and acne, menstrual irregularities, amenorrhea, sometimes hirsutism (deepening of the voice in women), and excess hair growth (in women). Prolonged or repeated eye contact with glucocorticoids/corticosteroids may affect vision (glaucoma, cataracts). Prolonged or repeated skin contact with corticosteroids/glucosteroids may cause dryness, folliculitis, acne, hypopigmentation, dermatitis, thinning of skin (skin atrophy). Corticosteroids may also have an inhibitory effect on wound healing. This may affect persons who have experienced recent nasal ulcers, nasal surgery or nasal trauma.

**Sensitization:** No information available.

**Mutagenic Effects:** No information available

**Carcinogenic effects:** Not considered carcinogenic.

Components	CAS-No.	IARC	ACGIH - Carcinogens	NTP	OSHA HCS - Carcinogens	Australia - Notifiable Carcinogenic Substances	Australia - Prohibited Carcinogenic Substances
Budesonide	51333-22-3	Not listed	Not listed	Not listed	Not listed	Not listed	Not listed

*ACGIH (American Conference of Governmental Industrial Hygienists)*

*IARC (International Agency for Research on Cancer)*

*NTP (National Toxicology Program)*

*OSHA (Occupational Safety and Health Administration of the US Department of Labor)*

**Reproductive toxicity** Suspected of damaging fertility or the unborn child

**Reproductive Effects:** No information available

**Developmental Effects:** May cause adverse developmental effects based on animal data

Possible risk of harm to the unborn child

Glucocorticoid medication used during pregnancy has been associated with an increased risk of cleft palate and impaired fetal growth by some studies (REPROTOX)

**Teratogenic Effects:** Corticosteroids are generally teratogenic in laboratory animals when administered systemically in doses substantially greater than those usually employed in humans. As there are no well controlled studies in women, the safety of their use in pregnant women has not been absolutely established

**Specific Target Organ Toxicity**

**STOT - single exposure** No information available.

**STOT - repeated exposure** No information available.

**Target Organs:** No information available.

**12. ECOLOGICAL INFORMATION**

**Ecotoxicity**

**Ecotoxicity effects:** No data available.

**Persistence and degradability:** No information available

**Bioaccumulative potential:** No information available.



**Mobility:** No information available.

### 13. DISPOSAL CONSIDERATIONS

#### Disposal Methods

**Waste from residues / unused products:**

Waste must be disposed of in accordance with Federal, State and Local regulation.

**Contaminated packaging:**

Empty containers should be taken for local recycling, recovery or waste disposal. Do not re-use empty containers  
Dispose of as unused product.

Components	CAS-No.	RCRA - F Series Wastes	RCRA - K Series Wastes	RCRA - P Series Wastes	RCRA - U Series Wastes
Budesonide	51333-22-3	None	None	None	None

### 14. TRANSPORT INFORMATION

#### DOT

**UN-No:** Not Regulated  
**Proper Shipping Name:** No information available  
**Hazard Class:** No information available  
**Subsidiary Class** No information available  
**Packing group:** No information available  
**Emergency Response Guide Number** No information available  
**Marine Pollutant** No data available  
**DOT RQ (lbs):** No information available  
**Special Provisions** No Information available  
**Symbol(s):** No information available  
**Description:** No information available

#### TDG (Canada)

**UN-No:** Not Regulated  
**Proper Shipping Name:** No information available  
**Hazard Class:** No information available  
**Subsidiary Risk:** No information available  
**Packing Group:** No information available  
**Marine Pollutant** No Information available  
**Description:** No information available

#### ADR

**UN-No:** Not Regulated  
**Proper Shipping Name:** No information available  
**Hazard Class:** No information available  
**Packing Group:** No information available  
**Subsidiary Risk:** No information available

#### IMO / IMDG

**UN-No:** Not Regulated  
**Proper Shipping Name:** No information available  
**Hazard Class:** No information available  
**Subsidiary Risk:** No information available  
**Packing Group:** No information available  
**Marine Pollutant** No information available

**RID**

**UN-No:** Not Regulated  
**Proper Shipping Name:** No information available  
**Hazard Class:** No information available  
**Subsidiary Risk:** No information available  
**Packing Group:** No information available

**ICAO**

**UN-No:** Not Regulated  
**Proper Shipping Name:** No information available  
**Hazard Class:** No information available  
**Subsidiary Risk:** No information available  
**Packing Group:** No information available

**IATA**

**UN-No:** Not Regulated  
**Proper Shipping Name:** No information available  
**Hazard Class:** No information available  
**Subsidiary Risk:** No information available  
**Packing Group:** No information available  
**ERG Code:** No information available  
**Special Provisions** No information available

<b>15. REGULATORY INFORMATION</b>
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**International Inventories**

Components	CAS-No.	U.S. TSCA	KOREA KECL	Philippines (PICCS)	Japan ENCS	CHINA	Australia (AICS)	EINECS-No.
Budesonide	51333-22-3	Not Listed	Not present	Not present	Not present	Not present	Not present	Present 257-139-7

**U.S. Regulations****California Prop. 65: Safe Drinking Water and Toxic Enforcement Act of 1986.****Chemicals Known to the State of California to Cause Cancer:**

This product does not contain a chemical requiring a warning under California Prop. 65. (See table below)

**Chemicals Known to the State of California to Cause Reproductive Toxicity:**

This product does not contain a chemical requiring a warning under California Prop. 65. (See table below)

Components	CAS-No.	Carcinogen	Developmental Toxicity	Male Reproductive Toxicity	Female Reproductive Toxicity:
Budesonide	51333-22-3	Not Listed	Not Listed	Not Listed	Not Listed

**CERCLA/SARA**

Components	CAS-No.	CERCLA - Hazardous Substances and their Reportable Quantities	Section 302 Extremely Hazardous Substances and TPQs	Section 302 Extremely Hazardous Substances and RQs	Section 313 - Chemical Category	Section 313 - Reporting de minimis
Budesonide	51333-22-3	None	None	None	None	None

**U.S. TSCA**

Components	CAS-No.	TSCA Section 5(a)2 - Chemicals With Significant New Use Rules	TSCA 8(d) -Health and Safety Reporting

Product code: B1595

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		<b>(SNURS)</b>	
Budesonide	51333-22-3	Not Applicable	Not Applicable

### Canada

**WHMIS hazard class:**

D2B Toxic materials  
D2A Very toxic materials

**Canada Controlled Products Regulation:**

This product has been classified according to the hazard criteria of the CPR (Controlled Products Regulation) and the MSDS contains all of the information required by the CPR.

**Inventory**

Components	CAS-No.	Canada (DSL)	Canada (NDSL)
Budesonide	51333-22-3	Not Listed	Not Listed

Components	CAS-No.	CEPA Schedule I - Toxic Substances
Budesonide	51333-22-3	Not listed
Components	CAS-No.	CEPA - 2010 Greenhouse Gases Subject to Mandatory Reporting
Budesonide	51333-22-3	Not listed

**EU Classification**

**R-phrase(s)**

R62 - Possible risk of impaired fertility.  
R63 - Possible risk of harm to the unborn child.  
R36/38 - Irritating to eyes and skin.

**S -phrase(s)**

S26 - In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.  
S28 - After contact with skin, wash immediately with plenty of water  
S36/37/39 - Wear suitable protective clothing, gloves and eye/face protection.

Components	CAS-No.	Classification	Concentration Limits:	Safety Phrases
Budesonide	51333-22-3		No information	

The product is classified in accordance with Annex VI to Directive 67/548/EEC

**Indication of danger:**

Xi - Irritant.

Xi



**16. OTHER INFORMATION**

Preparation Date: 8/2/2016  
Revision Date: 8/2/2016  
Prepared by: Sonia Owen

**Disclaimer:** All chemicals may pose unknown hazards and should be used with caution. This Safety Data Sheet (SDS) applies only to the material as packaged. If this product

is combined with other materials, deteriorates, or becomes contaminated, it may pose hazards not mentioned in this SDS. The physical properties reported in this SDS are obtained from the literature and do not constitute product specifications. Information contained herein does not constitute a warranty, whether expressed or implied, as to the safety, merchantability or fitness of the goods for a particular purpose. Spectrum Chemicals & Laboratory Products, Inc. assumes no responsibility for results obtained or for incidental or consequential damages, including lost profits, arising from the use of these data. No warranty against infringement of any patent, copyright or trademark is made or implied. It shall be the user's responsibility to develop proper methods of handling and personal protection based on the actual conditions of use. While this SDS is based on technical data judged to be reliable, Spectrum assumes no responsibility for the completeness or accuracy of the information contained herein.

**End of Safety Data Sheet**