

**Budesonide Inhalation Suspension Finished Product**  
**Material Safety Data Sheet**



1090 Horsham Road  
North Wales, PA 19454  
Effective: 10/16/2009

Telephone Calls: (201) 930-3411  
Emergency Contact: Chemtrec  
1-800-424-9300 24 hours

**SECTION 1 - IDENTIFICATION**

<b>PRODUCT NAME</b>	Budesonide Inhalation Suspension Finished Product	<b>SYNONYMS</b>	Pulmicort
<b>CHEMICAL FAMILY</b>	Corticosteroid	<b>THERAPEUTIC CATEGORY</b>	Antiinflammatory

**SECTION 2 – HEALTH HAZARD INFORMATION**

**EMERGENCY OVERVIEW**

DANGER – The information in this MSDS is based on the hazards of the active ingredient. While diluted, this material may present the following hazards - POTENTIAL TERATOGEN.

**EYE**

Contact may cause irritation and/or permanent eye damage.

**SKIN**

Contact may cause irritation.

**INGESTION**

Ingestion may cause irritation.

**INHALATION**

Breathing of dust may cause irritation to the respiratory tract.

**ADVERSE SYSTEMIC EFFECTS**

Hives or rash; swelling of the face, throat, or lips; wheezing or trouble breathing; rapid weight gain; rounded face; easy bruising, or unusual hair growth; swelling in hands, ankles, or feet; unusual tiredness, weakness or dizziness; headache; nausea, vomiting, or stomach pain/upset; new or increased acne; fever, chills, runny nose, cough, sneezing or congestion; nose bleed or dry mouth; sore throat; sores or white patches in mouth or throat; joint pain; worsening of asthma symptoms; insomnia.

**CHRONIC (CANCER) INFORMATION**

NTP – Not Listed  
IARC – Not Listed  
OSHA – Not listed

**REPRODUCTION INFO**

No adequate human studies have been conducted.

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**MEDICAL  
CONDITIONS/MEDS  
AGGRAVATED BY  
EXPOSURE**

Concomitant administration of other inhibitors of CYP3A4 may increase systemic exposure of Budesonide.

**TARGET ORGANS**

Hypothalamic Pituitary Adrenal (HPA).

**APPEARANCE**

Sterile Suspension for Nebulizer

**ODOR**

No information found.

**SECTION 3 – INGREDIENT INFORMATION**

<b>COMPONENT</b>	<b>CAS NUMBER</b>	<b>% BY WEIGHT</b>
Budesonide	51333-22-3	NA
Disodium Edetate	6381-92-6	NA
Sodium Chloride	7647-14-5	NA
Sodium Citrate	68-04-2	NA
Citric Acid	77-92-9	NA

**SECTION 4 – FIRST AID MEASURES**

**EYES**

Flush with large quantities of water for 15 minutes.

**SKIN**

Powders: Brush off material, remove contaminated clothing, flush with large quantities of water for 15 minutes.

**INGESTION**

Flush mouth with water – obtain medical attention.

**INHALATION**

Remove to fresh air.

**NOTE TO PHYSICIANS**

N/A

**SECTION 5 – FIRE FIGHTING MEASURES**

**FLAMMABLE  
PROPERTIES**

Material is assumed to be combustible. As with all dry powders, it is advisable to ground mechanical equipment in contact with dry material in order to dissipate static charges.

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**HAZARDOUS  
COMBUSTION  
PRODUCTS**

Emits toxic fumes under fire conditions.

**EXTINGUISHING  
MEDIA**

Water spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and materials.

**FIRE FIGHTING  
INSTRUCTION**

As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

**SECTION 6 – ACCIDENTAL RELEASE MEASURES**

**SMALL**

Wear appropriate PPE. Scoop up slowly without generating tablets and generating dust. (NO DRY SWEEPING). Wet wipe surfaces.

**SECTION 7 – HANDLING AND STORAGE**

**HANDLING**

Keep container closed, minimize dust generation during transfer.

**STORAGE**

Store in tight container.

**SECTION 8 – EXPOSURE CONTROL AND PPE**

**ENGINEERING  
CONTROLS**

Operations involving handling/transferring of dry power should be performed using containment measures (i.e. enclosures, etc.) and local exhaust ventilation.

**RESPIRATORY  
PROTECTION**

Wear appropriate PPE according to dust level.

**SKIN PROTECTION**

Wear appropriate PPE according to dust level.

**EYE PROTECTION**

Wear appropriate PPE according to dust level.

**COMPONENT**

Budesonide  
Disodium Edetate  
Sodium Chloride

**EXPOSURE LIMIT**

PIEL 2  $\mu\text{g}/\text{m}^3$ .  
No information found.  
No information found.

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Sodium Citrate  
Citric Acid

No information found.  
No information found.

**SECTION 9 – PHYSICAL AND CHEMICAL PROPERTIES**

<b><i>BOILING POINT</i></b>	No information found.	<b><i>MELTING POINT</i></b>	166 °C (API)	<b><i>pH</i></b>	No information found.
<b><i>VAPOR PRESSURE</i></b>	No information found.	<b><i>VAPOR DENSITY</i></b>			No information found.
<b><i>SOLUBILITY IN WATER</i></b>	Practically Insoluble. (API)	<b><i>ODOR</i></b>			No information found.
<b><i>APPEARANCE</i></b>	Suspension for Nebulizer.	<b><i>SPECIFIC GRAVITY</i></b>			No information found.
<b><i>AUTOIGNITION TEMPERATURE</i></b>	No information found.	<b><i>FLAMMABLE LIMITS</i></b>			No information found.
<b><i>MOLECULAR WEIGHT</i></b>	430.5 (API)	<b><i>FLASHPOINT</i></b>			N/A
<b><i>OCTANOL/WATER COEFFICIENT</i></b>	No information found.	<b><i>EVAPORATION RATE</i></b>			N/A

**SECTION 10 – STABILITY AND REACTIVITY**

<b><i>CHEMICAL STABILITY (CONDITIONS TO AVOID)</i></b>	This material is considered stable from a safety point of view.
<b><i>INCOMPATIBILITY</i></b>	No information found.
<b><i>HAZARDOUS DECOMPOSITION PRODUCTS</i></b>	When heated to decomposition, material emits toxic fumes.

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**HAZARDOUS  
POLYMERIZATION**

Will not occur.

**SECTION 11 – TOXICOLOGICAL INFORMATION**

**EYE**

No information found.

**SKIN**

TDLo 45.5 mg/kg skin administration rat. (API).

**INGESTION**

No Information found.

**INHALATION**

No Information found.

**ACUTE/SUBCHRONIC**

LD50 (>3200 mg/kg - oral rat). (API).

**MUTAGENICITY/  
CARCINOGENICITY**

Animal studies in rats have indicated an increase in hepatocellular tumors and gliomas, however at human equivalent doses, tumorigenicity was not observed (similar results to prednisolone and triamcinolone). Mutagenicity test battery was negative.

**REPRODUCTION**

Animal studies in rats and rabbits have indicated teratogenicity at low levels and embryocidal effects. Fertility impairment was not observed.

**SECTION 12 – ECOLOGICAL INFORMATION**

**ECOTOXICOLOGICAL  
INFORMATION**

No information found.

**CHEMICAL FATE  
INFORMATION**

Octanol water coefficient is  $1.6 \times 10^3$  @ pH of 5 for the API.

**SECTION 13 – DISPOSAL CONSIDERATIONS**

Dispose of in accordance with all applicable federal, state, and local regulations.

**SECTION 14 – TRANSPORTATION INFORMATION**

Finished products in final packaging ready for consumer use are NOT regulated by DOT.

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**SECTION 15 – REGULATORY INFORMATION**

<b>OSHA</b>	N/A
<b>CERCLA</b>	N/A
<b>SECTION 313 (SARA TITLE III)</b>	N/A
<b>OTHER REGULATIONS</b>	N/A

**SECTION 16 – OTHER INFORMATION**

<b>PREPARED BY</b>	Rob Mc Cafferty.
<b>REVISIONS</b>	New finished product MSDS.

**DISCLAIMER:**

*Teva Pharmaceuticals, Inc. provides the information contained in this MSDS sheet in good faith but makes no claim as to its accuracy or Comprehensiveness. This MSDS sheet is intended as a guide for a properly trained person to utilize appropriate precautionary methods while handling this product. Individuals must exercise their own judgment in determining the appropriateness of this information for a particular purpose. All MSDS sheets are subject to revision from time-to-time as new information becomes available. Anyone proposing to rely on information regarding the substance that is the subject of this MSDS sheet is responsible for ensuring that he or she has obtained and reviewed the most recent version of the sheet available at the time. Teva Pharmaceuticals, Inc. will not be responsible for damages resulting from the use or misuse of the information contained in this MSDS sheet.*