

Safety Data Sheet

Section 1. Identification

Common/Trade name : **Budesonide Nasal Spray**

Recommended use : Pharmaceutical industry: Dosage form
Therapeutic category: Anti-inflammatory corticosteroid.

This Safety Data Sheet has been provided to inform workers of the safety, health and environmental information associated with this product. It is to be used by people handling the material within the workplace only. It is not meant for patients taking the medication. Patients should consult with their physician, pharmacist or the information provided on the label or on the insert.

Recommended restrictions : No other uses are advised.

Supplier : **Canada**
Apotex Inc.
150 Signet Drive
Toronto, Ontario
M9L 1T9
416-749-9300

U.S.
Apotex Corp.
2400 N. Commerce Parkway
Suite 400
Weston, FLA 33326
Telephone: (954)384-8007
Toll Free: 1-800-706-5575

Emergency phone : United States/Canada (Chemtrec) 1-800-424-9300 or
+1 703-527-3887 (24 hours)
For general information call:
1-(416)-749-9300 ext. 8483 (8 AM-4 PM)

Section 2. Hazards Identification

Classification of the substance or mixture : As per 29 CFR 1910.1200 (b)(6) and according to Article 1, item 5 a) of CLP Regulation (EC) 1272/2008, medicinal products (drugs) when it is in the solid, final form for direct administration to the patient or are packaged by the manufacturer for sale to consumers in a retail establishment are exempt from the requirements of classification, labels and SDS's.

GHS label elements : Exempt from requirements.

Hazards not otherwise classified : Exempt from requirements.

Section 3. Composition/Information on Ingredients

Name	CAS #	% (w/w)
Budesonide	51333-22-3	<0.5

Specific chemical identity and/or percentage of composition has been withheld as a trade secret.

Chemical name : Not applicable.

Synonyms : Not available.

Chemical family : Corticosteroid

Molecular weight : Not applicable.

Chemical formula : Not applicable.

Section 4. First Aid Measures

- Eye contact** : Flush with copious quantities of water. If irritation persists, obtain medical advice.
- Skin contact** : Flush with copious amounts of water. Seek medical attention if irritation persist.
- Inhalation** : Remove from exposure. Persons developing serious hypersensitivity reactions must receive immediate medical attention. If not breathing give artificial respiration. If breathing is difficult give oxygen.
- Ingestion** : Never give anything by mouth if victim is losing consciousness, or is unconscious or convulsing. Rinse mouth thoroughly with water. If breathing is difficult, give oxygen. If breathing has stopped, trained personnel should begin artificial respiration, or if the heart has stopped, cardiopulmonary resuscitation (CPR) immediately. Seek medical attention.
- Potential acute and delayed health effects** : Refer to Sec. 11

Section 5. Fire Fighting Measures

- Specific hazard arising from the chemical** : During fire, gases hazardous to health may be formed.
- Suitable extinguishing media and special protective equipment for firefighters** : Extinguisher media: Use extinguishing media suitable for surrounding materials.
Special fire fighting procedures: As with all fires, evacuate personnel to safe area. Firefighters should use self-contained breathing equipment and protective clothing.

Section 6. Accidental Release Measures

- Methods and materials for containment and cleaning up** : Contain and clean up spillage and place into an appropriate labeled waste disposal container. Avoid generating dust or aerosols. Wash spill surface using appropriate cleaning solutions. Should clothing be contaminated, wash before reuse.
- Protective equipment and personal precautions** : Keep unnecessary personnel away. Wear appropriate personal protective equipment. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. For personal protection, refer to section 8 of the SDS.

Section 7. Handling and Storage

- Precautions for safe handling** : Avoid contact with eyes.
- Conditions for safe storage** : Store at controlled room temperature 20-25°C (68-77°F). Protect from light. Do not freeze. Protect from light.

Section 8. Exposure Controls/Personal Protection

- Engineering Controls** : The engineering control measures appropriate for a particular worksite depend on how this material is handled and on the extent of exposure. Ensure that control measures are designed to comply with occupational, environmental, fire and other applicable regulations. Control measures can include mechanical ventilation (local or general) and process enclosure. Administrative controls and personal protective equipment may also be required.

Personal Protection	: Follow all appropriate safe work procedures and local regulations for disposal. Use only licensed disposal and waste hauling companies. PERSONAL PROTECTIVE EQUIPMENT/RESPIRATORY PROTECTION GUIDELINES: Under normal work conditions, the use of respiratory protective equipment is not expected to be required. If the physical state of the finished product is altered by crushing, grinding or breakage or for spill cleaning, appropriate PPE may be required that includes NIOSH approved respirators. EYE/FACE PROTECTION: Wear approved safety eyewear if eye contact is possible. SKIN PROTECTION: Where there is a risk of contact when handling, wear suitable skin protection (e.g., gloves, lab coat/uniform) having resistance to the product. HYGIENE MEASURES: In the event clothing becomes contaminated, remove promptly. Launder before use. When handling, do not eat, drink or smoke. Wash hands thoroughly after handling this material. Maintain good housekeeping.
Occupational exposure limits	: Not established.

Section 9. Physical and Chemical Properties

Physical state and appearance	: Liquid. (suspension.)		
pH	: Not available.	Odor	: Not available.
Melting point/Freezing point	: Not available.	Odor threshold	: Not available.
Boiling point	: Not available.	Conditions of instability	: No additional remark.
Volatility	: Not available.	Decomposition temperature	: Not available.
Specific gravity	: Not available.	Partition Coefficient:	: Not available.
Evaporation rate	: Not available.	Viscosity	: Not available.
Vapor density	: Not available.	Flash points	: Not applicable.
Relative density	: Not available.	Flammable limits	: Not applicable.
Vapor pressure	: Not available.	Autoignition temperature	: Not applicable.
Flammability	: Not applicable.		
Solubility	: Not available.		

Section 10. Stability and Reactivity

Reactivity	: Not available.
Chemical Stability	: Stable under recommended conditions of use.
Possibility of hazardous reactions	: Not available.
Hazardous decomp. products	: When heated to decomposition material emits toxic fumes.

Incompatible materials/ Conditions to avoid : Not available.

Section 11. Toxicological Information

Information on the likely routes of exposure : Ingestion. Inhalation.

Toxicity data : RTECS#: TU3723000
LD50: >3200 mg/kg (oral-rat)
LD50: 4750 mg/kg (oral-mouse)

Delayed and immediate effects and also chronic effects from short and long term exposure : Target Organs: Endocrine system.
Carcinogenicity: Not listed as carcinogen by IARC, NTP, ACGIH, or OSHA. Long-term carcinogenicity studies in Sprague-Dawley rats given 50 microgram/kg doses of budesonide had mixed results. One study showed an increased incidence of gliomas (tumors of the brain or spine) and another study showed an increased incidence of hepatocellular tumors in male rats. However, other studies have not shown tumorigenicity at this dose in Fischer and Sprague-Dawley rats. Budesonide was not carcinogenic in a 91-week study in mice give 200 micrograms/kg orally.
Reproductive Toxicity: Overexposure may cause reproductive disorder based on tests with laboratory animals.

Teratogenicity: Pregnancy Category C: Budesonide was teratogenic and embryocidal in rabbits and rats. Budesonide produced fetal loss, decreased pup weights, and skeletal abnormalities at subcutaneous doses of 25 mcg/kg in rabbits and 500 mcg/kg in rats (approximately 2 and 16 times the maximum recommended daily intranasal dose in adults on a mcg/m² basis). In another study in rats, no teratogenic or embryocidal effects were seen at inhalation doses up to 250 mcg/kg (approximately 8 times the maximum recommended daily intranasal dose in adults on a mcg/m² basis).

Mutagenicity: Budesonide was not mutagenic or clastogenic in the Ames Salmonella/microsome plate test, the mouse micronucleus test, the mouse lymphoma test, the human lymphocyte chromosome aberration test, the sex-linked recessive lethal test in *Drosophila melanogaster*, and the DNA repair analysis in rat hepatocyte culture.

Remark

Medical conditions aggravated by exposure: Hypersensitivity to material, heart disease, high blood pressure, diabetes, epilepsy, glaucoma, hypothyroidism, osteoporosis, peptic ulcer, mental disorders, or impaired liver or kidney function. Persons sensitive to one corticosteroid may be sensitive to this material also.

Symptoms related to the physical, chemical and toxicological characteristics : The following most common adverse reactions were reported in clinical trials: epistaxis, pharyngitis, bronchospasm, coughing, nasal irritation. Chronic overdosage may result in signs/symptoms of hypercorticism.

Section 12. Ecological Information

Ecotoxicity : Not available.

Persistence and degradability : Not available.

Bioaccumulative potential : Not available.

Mobility in soil : Not available.

Other adverse effects : Not available.

Section 13. Disposal Considerations

Waste Disposal : Follow all appropriate safe work procedures and local regulations for disposal. Use only licensed disposal and waste hauling companies.

Section 14. Transport information

Regulatory information	UN number	Proper shipping name	Class	Packing group	Label	Additional information (e.g., special precautions, environmental hazards, transport in bulk)
TDG- road Canada/U.S.			Not regulated.			
ICAO-Air			Not regulated.			
ADR			Not regulated.			
IMDG Class			Not regulated.			

Section 15. Regulatory Information

Canada Regulations : Covered by Food & Drug Act and therefore not regulated under WHMIS
Not on the DSL list.

Other Regulations : Not available.

Section 16. Other Information

References : RTECS Database
PDR Electronic Library
Apotex Product Monograph
U.S. Pharmacopeia

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Notice to Reader

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