

SAFETY DATA SHEET

Product : Budesonide Inhalation Suspension 0.5mg/2.0ml
Date of Issue : 18.11.2015
NDC No. : NDC 781-7516-XX

Revision No. : 02

1 IDENTIFICATION OF SUBSTANCE

Product Identifier : Budesonide Inhalation Suspension 0.5mg/2ml

Other means of identification

Catalog number : Information not available

Chemical name : Information not available

Synonym(s) : Information not available

Company : Cipla Limited

Head Office : Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai, Maharashtra, India (Pin Code – 400 013)

Manufacturing division : Cipla Ltd., L-139 to L-146, Verna Industrial Estate, Verna, Salcette Goa – 403 722 India

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Recommended use : It is an anti-inflammatory drug (corticosteroid hormone). It works by decreasing the body's natural defense response (immune response).

Recommended restrictions : It may cause a serious type of allergic reaction called anaphylaxis. Anaphylaxis requires immediate medical attention. The most serious signs of this reaction are very fast or irregular breathing, gasping for breath, wheezing, or fainting. Other signs may include changes in color of the skin of the face, very fast but irregular heartbeat or pulse, hive-like swellings on the skin, and puffiness or swellings of the eyelids or around the eyes

2 HAZARD IDENTIFICATION

Classification as per EC -

Physical : Data not available.

Health : Data not available.

Environmental : Data not available

Label in accordance with EC : This product is a non-hazardous solution of single components and need not be labelled according to EC-Directive 1999/45/EC, as amended.

Single Word : Budesonide Inhalation Suspension

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Contains	: Budesonide (Micronised), Polysorbate 80, Sodium Chloride, Citric Acid (Monohydrate), Disodium Edetate, Sodium Citrate Dihydrate and Water for Injection.
Hazard Statements	: Contains a pharmaceutical active ingredient
Precautionary Statements	: Wear suitable protective clothing and gloves.
Prevention	: Data not available
Response	: If conscious, give water to drink and induce vomiting Wash out the mouth with water. Obtain medical attention
Storage	: Keep in closed containers at room temperature.
Disposal	: Dispose of contents/container in accordance with local/regional/national/international regulations.
Supplemental Hazard	: Information not available.
Statements	: Information not available.

3 COMPOSITION / INFORMATION ON INGREDIENTS
Budesonide (Micronised) -

Chemical Name	: 16,17-(butylidenebis(oxy))-11,21-dihydroxy-, (11-β,16-α)-pregna-1,4-diene-3,20-dione
Molecular Formula	: C ₂₅ H ₃₄ O ₆
Molecular Weight	: 430.53 g/mol
CAS No.	: 51333-22-3
UN. No.	: Information not available.
EC No.	: Information not available.

4 FIRST AID MEASURES

General advice	: Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures
Skin Contact	: May cause irritation. Flush with copious amounts of water. Seek medical advice. Flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes.

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Eye Contact	: Immediately flush eyes with plenty of water for at least 15 minutes, occasionally lifting the upper and lower eyelids.
Ingestion	: If conscious, give water to drink and induce vomiting. Wash out the mouth with water. Obtain medical attention.
Inhalation	: Remove from exposure and move to fresh air immediately.
Indication of immediate medical attention and special treatment needed	: Information not available

5 FIRE FIGHTING MEASURES

Fire and Exposure hazard	: Information not available
Extinguishing media	: Use water spray, carbon dioxide or dry chemical.
Special fire fighting procedures	: Wear self-contained breathing apparatus (SCBA) and full turnout gear. As with all fires, evacuate person to safe area equipment are recommended for fire-fighters.
Hazardous Combustion Products	: Information not available

6 ACCIDENTAL RELEASE MEASURES

Personal Precautions	: Avoid unwanted exposure, where self contained breathing apparatus or approved respirator whichever is suitable, chemical suit, chemically compatible hand gloves and boots.
Environmental Precaution	: Vacuum up the material, place in a bag / container and hold for waste disposal. Place spillage in appropriate container / bag for waste disposal. Wash contaminated clothing before reuse.
Clean-up Procedure	: Ventilate area and wash spill site. Dispose off waste in accordance with applicable federal state and local laws.
Decontamination Procedure	: Information not available.

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7 HANDLING AND STORAGE	
Handling	: Handle material with care. This material should be handled as per instructions to ensure product integrity. Avoid contact with skin, eyes and clothing. Handle product with wearing proper personnel protective equipments mentioned in section. Wear fresh clothing daily. Wash contaminated clothing before reuse. Wash thoroughly after handling. Do not permit eating, drinking or smoking near the material.
Storage	: Closed container at the demarcated place. This material should be handled and stored as per instructions to ensure product integrity.
8 EXPOSURE CONTROLS / PERSONAL PROTECTION	
Exposure limit values	: Information not available.
Respiratory protection	: Wear a NIOSH/MSHA or European Standard EN 149 approved full face piece.
Hand protection	: Wear chemical compatible hand gloves.
Eye protection	: Wear safety glasses and chemical goggles if splashing is possible.
Skin protection	: Wear appropriate laboratory apparel. Protect exposed skin.
Exposure control/Ventilation	: Adequate ventilation is required .Provide local exhaust and mechanical ventilation.
Hygiene Measure	: Information not available
9 PHYSICAL AND CHEMICAL PROPERTIES	
Appearance and odour	: A white to off white homogeneous redispersible suspension.
Vapour pressure	: Information not available
Vapour density	: Information not available
Flash point	: Information not available
Viscosity	: Information not available
Boiling point	: Information not available
Melting range	: Information not available
Specific gravity	: Information not available
Auto-ignition	: Information not available

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Relative density	: Information not available
Flammability	: Information not available
Solubility	: Information not available

10 STABILITY AND REACTIVITY

Stability	: Information not available.
Reactivity	: Information not available.
Incompatibilities / Conditions to avoid	: Information not available.
Hazardous decomposition products	: Information not available.
Hazardous reactions	: Information not available.
Hazardous polymerization	: Information not available.

11 TOXICOLOGICAL INFORMATION

Health Hazard	: Information not available
Acute Toxicity	: Information not available
Oral Toxicity	: Information not available
Sensitization	: Information not available
Inhalation Toxicity	: Information not available
Genetic Toxicity	: Information not available
Skin Effects	: Information not available
Carcinogenicity	: Information not available
Eye Effects	: Information not available
Reproductive effects	: Information not available
Target Organ Effects	: Information not available
<u>Toxicity data -</u>	
SCU-RAT LD 50	: Information not available
LD 50 (Oral, mouse)	: >3200mg/kg (Budesonide)
LD 50 (Oral, mouse)	: 4750mg/kg (Budesonide)

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LD 50 (intraperitoneal, mouse)	: 179mg/kg (Budesonide)
12 ENVIRONMENTAL / ECOLOGICAL INFORMATION	
Summary	: Releases to the environment should be avoided.
Ecotoxicity	: Information not available.
Degradability	: Information not available
13 DISPOSAL CONSIDERATION	
Disposal Recommendations	: Dispose material as per local, state and federal regulatory procedures and laws.
Regulatory Requirements	: Information not available.
14 TRANSPORT INFORMATION (Un Classification and Labelling)	
DOT UN number	: Information not available.
UN proper shipping name	: Information not available.
Transport hazard class(es)	: Information not available.
Subsidiary class(es)	: Information not available.
Packing group	: Information not available.
IATA	
UN number	: Information not available.
UN proper shipping name	: Information not available.
Transport hazard class(es):	: Information not available.
Subsidiary class(es)	
Packing group	: Information not available.
Other Information	: This is a Pharmaceutical Product there are no restrictions for transportation.
15 REGULATORY INFORMATION	
Labelling according to EEC directives	: Information not available.
National legislation/regulations	: Information not available.

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Any other regulatory Information:

US state regulations : This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins

16 OTHER INFORMATION

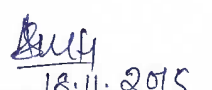
Therapeutic Category of material : Corticosteroid

Reference : As per API and excipient Vendor Material MSDS

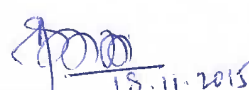
The information contained herein is based on the present state of our knowledge and does not therefore guarantee certain properties. The information given was obtained from sources which we believe are reliable. The information and recommendations given are to the best of our knowledge and as per data given by Quality assurance, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. Recipients of material must take responsibility for observing existing laws, regulations and suitability of material for handling transport and any particular purpose. We do not assume responsibility and expressly disclaim liability for loss, damage and expenses arising out of or in any way connected with the handling storage, use and disposal of the product information mentioned in this document relates only to the specific material designated and may not be valid for such material used in combination with other material or in any process.



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Safety



Approved By
Head Unit Quality



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