

SAFETY DATA SHEET

Product : Budesonide Inhalation Suspension 1.0mg/2.0ml	Revision No. : 01
Date of Issue : 09.05.2017	
NDC No. : NDC 69097-321-87	

1 IDENTIFICATION OF SUBSTANCE

Product Identifier : Budesonide Inhalation Suspension 1.0mg/2ml

Synonym(s) : Not Applicable

Company Name : Cipla Limited

Company Address: 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). 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

Recommended restrictions : 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

Hazard Statements : Contains a pharmaceutical active ingredient

Precautionary Statements : Wear suitable protective clothing and gloves.

Description of any hazards not otherwise classified : Data not available.

Sanjay Ghare
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% of the mixture consisting of ingredient(S) with unknown acute toxicity : Data not available.

3 COMPOSITION / INFORMATION ON INGREDIENTS

Chemical Name	: 22S and 22R epimers of 16a,17a-butylidenedioxy-11b,21-dihydroxypregna-1,4-diene-3,20-dione
Common Name / Synonyms	: Budesonide
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.
Mixture (Ingredient Name, Concentration)	: Polysobrate 80, Sodium Chloride, Edetate Disodium , Citric acid monohydrate, Sodium Citrate Dihydrate and Water for Injection
Chemicals where a trade secret is claimed	: 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
Inhalation	: Remove from exposure and move to fresh air immediately.
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.
Eye Contact	: Immediately flush eyes with plenty of water for at least 15 minutes, occasionally lifting the upper and lower eyelids.

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Ingestion : If conscious, give water to drink and induce vomiting. Wash out the mouth with water. Obtain medical attention.

NOTES TO HEALTH PROFESSIONALS

Medical Treatment : Information not available
Medical conditions : Information not available
caused or aggravated by exposure Antidote : Information not available

5 FIRE FIGHTING MEASURES

Fire and Exposure hazard : The product is assumed to be combustible. Emits toxic fumes under fire condition.
Extinguishing media/ equipment : Use water spray, carbon dioxide or dry chemical.
Special firefighting procedures and Protective Measures : 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, wear self-contained breathing apparatus or approved respirator whichever is suitable, chemical suit, chemically compatible hand gloves, boots and safety goggles.
Environmental Precaution : Vacuum up the material, place in a bag / container and hold for waste disposal.
Clean-up Procedure : Place spillage in appropriate container / bag for waste disposal. Wash contaminated clothing before reuse. Ventilate area and wash spill site. Dispose off waste in accordance with applicable federal state and local laws.
Decontamination Procedure : Information not available.
Methods and materials used for containment : Contain spill and collect, as appropriate.
Emergency Procedures : Information not available.

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7 HANDLING AND STORAGE

Precautions for Safe 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.
Safe Storage	: Closed container at the demarcated place. This material should be handled and stored as per instructions to ensure product integrity.
Any Specific storage requirements	: Store in accordance with information listed on the product insert.

8 EXPOSURE CONTROLS / PERSONAL PROTECTION

Hazard category and Exposure limits	: Information not available.
Appropriate Engineering Controls	: Use process enclosures, local exhaust ventilation, or other engineering controls to control airborne levels below recommended exposure limits.
Respiratory protection equipment	: Wear a NIOSH/MSHA or European Standard EN 149 approved full face piece.
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

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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
Relative density	: Information not available
Flammability	: Information not available
Solubility	: Information not available
Explosive Limits	: Information not available
Odour threshold	: Information not available
pH	: Information not available
Freezing Point	: Information not available
Evaporation Rate	: Information not available
Partition Coefficient	: Information not available
Decomposition Temperature	: Information not available

10 STABILITY AND REACTIVITY

Chemical 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

Symptoms on Exposure	: Information not available.
Route of Exposure	: Absorbed through skin, Eye contact, Inhalation, Ingestion.
Oral Toxicity	: Information not available

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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
SCU-RAT LD 50	: Information not available
LD 50 (Oral, mouse)	: >3200mg/kg (Budesonide)
LD 50 (Oral, mouse)	: 4750mg/kg (Budesonide)
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

Description of appropriate disposal container to Use	: Information not available
Disposal method Recommendations	: Dispose material as per local, state and federal regulatory procedures and laws.
Physical and Chemical properties that can affect Disposal	: Dispose material as per local, state and federal regulatory procedures and laws.
Any Special Precautions to be taken	: Information not available

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Regulatory Requirements : Information not available.

14 TRANSPORT INFORMATION (Un Classification and Labelling)

UN number : Information not available.
UN proper shipping name : Information not available.
ADR Packing Group : Information not available.
ADR Class : Information not available.
Additional Pictogram : Information not available.
ADR : Information not available.
IATA : Information not available.
GHS : Information not available.
Environmental Hazards : Releases to the environment should be avoided.
Any Special Precaution (If any) : 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.
Any other regulatory Information : Irritating to eyes, respiratory system and skin. Possible risks of irreversible effects. Possible risk of harm to the unborn child.

16 OTHER INFORMATION

SDS Prepared On : 09.05.2017
Last Revision done date : Not Applicable
Changes done to previous version : Not Applicable
Therapeutic Category of material : Anti-Asthma drug
Reference : As per API and excipient Vendor Material MSDS

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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.



Prepared By
Safety

Date : 09.05.2017



Approved By
Head Unit Quality

Date : 09.05.2017



Noted By
Unit Head

Date : 09.05.2017