

SAFETY DATA SHEET

Product : Ipratropium bromide 500mcg/3ml and Albuterol Sulfate 3mg/3ml Inhalation Solution
Date of Issue : 04.07.2015 Revision No. : 01

1 IDENTIFICATION OF SUBSTANCE

Trade Name : Ipratropium bromide 500mcg/3ml and Albuterol Sulfate 3mg/3ml Inhalation Solution

Company : Cipla Ltd.

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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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 : Ipratropium bromide and Albuterol Sulphate

Contains : Ipratropium bromide, Albuterol Sulphate, Sodium Chloride, Edetate Disodium, Hydrochloric Acid, Water for Injection

Hazard Statements : Contains a pharmaceutical active ingredient

Precautionary Statements : Wear suitable protective clothing and gloves.

Supplementary Precautionary Statement : data not available.

3 COMPOSITION / INFORMATION ON INGREDIENTS

Ipratropium Bromide -

Chemical Name : 1-alpha-H,5-alpha-H-Tropanium, 3-alpha-hydroxy-8-isopropyl-, bromide, (+-)-tropate

Molecular Formula : C₂₀ H₃₀ N O₃. Br. H₂O

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Molecular Weight : 430.38
CAS No. : 66985-17-9
UN. No. : Information not available.
EC No. : Information not available.

Albuterol Sulphate -

Chemical Name : Di [(RS) - 2 - (1, 1 - dimethyl) ethylamino
- 1 - [4 - hydroxy - 3 - (hydroxymethyl)
phenyl] ethanol] Sulphate
Molecular Formula : (C₁₃ H₂₁ NO₃)₂ . H₂SO₄
Molecular Weight : 476.70
CAS No. : 51022-70-9
UN. No. : Information not available.
EC No. : 256-916-8

4 FIRST AID MEASURES

General advice

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.

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.

NOTES TO HEALTH PROFESSIONALS

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

5 FIRE FIGHTING MEASURES

Fire and Exposure hazard : Information not available

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Extinguishing media : Use water spray, carbon dioxide or dry chemical.
Special fire fighting 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, 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.
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.

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 -
1. Bulk Storage : Closed container at the demarcated place. This material should be handled and stored as per instructions to ensure product integrity.
2. Department Storage : As above
Pictograms : Information not available.

8 EXPOSURE CONTROLS / PERSONAL PROTECTION

Hazard category and Exposure Limits : Information not available.

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Personal Protective equipment

Respiratory protection : Wear a NISOH/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 : Adequate ventilation is required .Provide local exhaust and

Ventilation : mechanical ventilation.

Hygiene Measure : Information not available

9 PHYSICAL AND CHEMICAL PROPERTIES

Appearance and odour : A clear, colourless solution

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

Relative density : Information not available

Flammability : Information not available

Solubility : Information not available

10 STABILITY AND REACTIVITY

Stability : Information not available.

Incompatibilities / Conditions to avoid : Information not available.

Hazardous decomposition products : Information not available.

Hazardous reactions : Information not available.

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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

Toxicity data -

SCU-RAT LD 50 : 1.722 mg/kg rat (male/female) The values mentioned are those of the active ingredient. (Ipratropium Bromide)

SCU- MUS LD 50 : 1.038 mg/kg mouse (male/female) The values mentioned are those of the active ingredient. (Ipratropium Bromide)

SCU-RAT LD 50 : > 2.000,000 mg/kg rat. The values mentioned are those of the active ingredient. (Albuterol Sulfate)

SCU- MUS LD 50 : 3.800,000 mg/kg mouse. The values mentioned are those of the active ingredient. (Albuterol Sulfate)

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.

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14 TRANSPORT INFORMATION (Un Classification and Labelling)

ADR packing Group : Information not available.
ADR Class : Information not available.
Additional Pictogram : Information not available.
Other Information : This is a Pharmaceutical Product there are no restrictions for transportation.

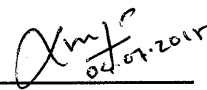


15 REGULATORY INFORMATION

Labelling according to EEC directives : Information not available.
National legislation / regulations : Information not available.
Any other regulatory Information : Information not available.

16 OTHER INFORMATION

Therapeutic Category of material : Bronchodilator
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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