

**MATERIAL SAFETY DATA SHEET**

**Product** : Albuterol Sulfate Inhalation Aerosol (90 mcg/spray) (200 Metered Inhalations)  
**Date of Issue** : 09.04.2020 **Revision No.** : 01

**1 IDENTIFICATION OF SUBSTANCE**

**Trade Name** : Albuterol Sulfate Inhalation Aerosol (90 mcg/spray)  
**Company** : Cipla Ltd., Plot No. 9, Pharma zone, Phase II, Sector III, Indore Special Economic Zone Pithampur, Dist: Dhar, Madhya Pradesh-454775

**Telephone** : +91 2225712463 **Fax** : +91 227913111  
**E-mail** : Dsafe@cipla.com **Web site** : www.cipla.com  
**Emergency Contact** : +91 2225712463

**2 HAZARD IDENTIFICATION**

**Classification as per EC -**  
**Physical** : Clear, Colourless and Odorless solution.  
**Health** : Product May be mildly harmful if overdose.  
**Environmental** : Information Not Available

**Label in accordance with EC** – Information not available

**Single Word** – Non Hazardous

**Contains** – API – Albuterol Sulfate, Dehydrated alcohol, Oleic Acid and 1,1,1,2-Tetrafluoroethane

**Hazard Statement** – Non Hazardous substance

**Precautionary Statements** – Information not available

**Supplementary Precautionary Statement** – Information not available

**3 COMPOSITION / INFORMATION ON INGREDIENTS**

Albuterol Sulfate, Dehydrated alcohol, Oleic Acid and Propellant-134a

**Chemical Name** :  $\alpha$  1-[tert-butylamino)-methyl]-4-hydroxy-m-xylene- $\alpha$  -  $\alpha$  ' -diol sulfate (2:1) (salt)

**Albuterol Sulfate** : (C13H21NO3)2•H2SO4

**Molecular Formula**

**Dehydrated Alcohol** : C2H6O

**Molecular Formula**

**Oleic Acid Molecular** : C18H34O2

**Formula**

**1,1,1,2-** : CH2FCF3

**Tetrafluoroethane**

**Molecular Formula**

**Molecular Weight of** : 576.71g/mole

**Albuterol Sulfate**

**Molecular Weight of** : 46.06844 g/mole

**Dehydrated Alcohol**

**Molecular Weight of** 282.4614 g/mole

**Oleic Acid**

**Molecular Weight of** 102.03 g/mole

**1,1,1,2-**

**Tetrafluoroethane**

**CAS No** : 51022-70-9

**UN No.** : Information not available **EC No.** : Information not available

**of**

**Albuterol**

*Handwritten signature and date:*  
09.04.2020

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<b>Sulfate</b>					
<b>CAS No</b>	: 64-17-5	<b>UN No.</b>	: Information not available	<b>EC No.</b>	: Information not available
<b>of Dehydrated Alcohol</b>					
<b>CAS No</b>	: 112-80-1	<b>UN No.</b>	: Information not available	<b>EC No.</b>	: Information not available
<b>of Oleic Acid</b>					
<b>CAS No</b>	: 811-97-2	<b>UN No.</b>	: Information not available	<b>EC No.</b>	: Information not available
<b>of 1,1,1,2-Tetrafluoroethane</b>					

**Ingredients** : Albuterol Sulfate, Dehydrated Alcohol, Oleic Acid, 1,1,1,2-Tetrafluoroethane

**4 FIRST AID MEASURES**

**General advice:** Keep out of reach of children

**Inhalation** : If unintentional inhalation or overdose occurs, remove person to fresh air and seek medical attention. If individual has trouble breathing, seek medical attention immediately.

**Skin Contact** : Wash affected areas with soap and water after removing contaminated clothing. Obtain medical attention, if symptoms or irritation persist.

**Eye Contact** : Flush affected eye(s) with large amounts of potable water for at least 15 minutes. Obtain medical attention.

**Medical Treatment:** Treat symptomatically.

**Medical conditions caused or Aggravated by exposure** : Information not available

**Antidote** : Not applicable

**5 FIRE FIGHTING MEASURES**

**Fire and Explosion hazard** : Product is Not Flammable

**Extinguishing media** : Not Applicable

**Special fire fighting procedure and Protective Measures** : Not Applicable

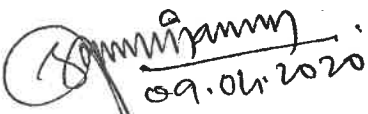
**Hazardous Combustion Products** : Not applicable

**6 ACCIDENTAL RELEASE MEASURES**

**Personal Precautions** : Use appropriate PPE's to avoid exposure.

**Environmental Precaution** : Dispose of waste material at an approved waste treatment facility in accordance with applicable local and federal regulation.

**Spill Clean - up Procedure** : Wash spill area with soap and water.

  
09.06.2020

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**Decontamination Procedure** : No specific decontamination procedure has been identified.

**7 HANDLING AND STORAGE**

**Handling** : Avoid contact with eyes, skin, and clothing.

**Storage** : Protect from light and excessive heat. Store between 15-25°C (59°-77° F).

1. **Bulk Storage** – Information not available
  2. **Department Storage** – Information not available
- Pictograms** – Information not available

**8 EXPOSURE CONTROLS / PERSONAL PROTECTION**

**Hazard category and Exposure Limits:-**

For albuterol sulfate the estimated safe working level is 10 mcg/m<sup>3</sup> for an eight hour time-weighted average.

**Personal protective equipment:-**

Refer to national standards and regulation in the selection and use of personal protective equipment.

**Ensure before use** – Wash hands after handling and before eating.

**Respiratory protection** : Information not available  
**Hand protection** : NA  
**Eye protection** : NA  
**Skin protection** : NA  
**Exposure control Ventilation** : NA  
**Hygiene Measure** : Handle in accordance with good industrial hygiene practice

**9 PHYSICAL AND CHEMICAL PROPERTIES**

**Appearance and odour** : Clear, Colourless and Odorless solution.  
**Vapor pressure** : NA **Vapor density** : NA  
**Flash point** : NA **Viscosity** : NA  
**Melting range** : NA **Boiling point** : 100°C  
**Specific gravity** : 1 **Auto-ignition** : NA  
**Relative density** : NA **Flammability** : NA  
**Solubility** : 100% in water

**10 STABILITY AND REACTIVITY**

**Stability** : Stable  
**Incompatibilities / Conditions to avoid** : Avoid to contact with strong acids, bases, or oxidizers.  
**Hazardous decomposition products** : Not determined  
**Hazardous reactions** : Not determined  
**Hazardous polymerization** : Not determined

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**11 TOXICOLOGICAL INFORMATION**

<b>Oral Toxicity</b>	: Not Applicable	<b>Sensitization</b>	: Rarely, exposure can cause an allergic rash with redness and itching of the skin.
<b>Inhalation Toxicity</b>	: inhalation can cause an allergic rash, difficulty breathing and swelling of the face and airways.	<b>Genetic Toxicity</b>	: Information not available
<b>Skin Effects</b>	: May cause skin effect	<b>Carcinogenicity</b>	: Information not available
<b>Eye Effects</b>	: May cause eye irritation	<b>Reproductive Effects</b>	: Information not available
<b>Target Organ Effects</b>	: Information not available		
<b>Toxicity data</b> : Information not available			
<b>ORL - RAT LD 50</b>	: Information not available	<b>SCU - RAT LD 50</b>	: Information not available
<b>ORL -MICE LD 50</b>	: Information not available	<b>SCU - MUS LD 50</b>	: Information not available

**12 ENVIRONMENTAL / ECOLOGICAL INFORMATION**

**Summary** : Information not available  
**Eco toxicity** : It has toxicity to receptors in the aquatic environment at levels greater than 83.2 mg/L.  
**Degradability**: Albuterol is not readily biodegradable in water or soil and is unlikely to bio accumulate.

**13 DISPOSAL CONSIDERATION**

**Disposal Recommendations** : - Dispose of waste material at an approved waste treatment facility in accordance with applicable local and federal regulation.  
**Regulatory Requirements** : Follow local and federal regulation

**14 TRANSPORT INFORMATION (UN Classification and Labeling )**

Safety Data Sheet should accompany all shipments for reference in the event of spillage or accidental release.  
**ADR Packing Group** – Not available                      **ADR Class** – Not available  
**Additional Pictogram** - Not available

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**ADR IATA GHS**

**Other Information** : Not Classified.

**15 REGULATORY INFORMATION**

**Labeling according to EEC directives  
National legislation / regulations**

: Albuterol is not listed under the Chemicals  
(Hazard Information and Packaging)  
Regulations, 1993. However, suitable labelling  
may be used.

**Any other regulatory information**

: Wear suitable protective clothing and gloves.

**16 OTHER INFORMATION**

**Therapeutic category of Material** : Not Available

**Reference** : MSDS of API, Proventil PIL,MSDS of Proventil HFA

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, 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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09.04.2020