SAFETY DATA SHEET

According to Globally Harmonized System of Classification and Labelling of Chemicals (GHS), Eighth Revised Edition UNITED NATIONS New York and Geneva, 2019

FORMOTEROL FUMARATE INHALATION SOLUTION, 20 MCG/2 ML (0.02 MG/2 ML)

1. IDENTIFICATION

GHS Product identifier: Formoterol fumarate inhalation solution

Product code: #

Chemical Description: (±)-2′-Hydroxy-5′-[(R*)-1-hydroxy-2-[[(R*)-p-methoxy-αmethylphenethyl]amino]ethyl]formanilide fumarate (2:1) (salt), dihydrate

Other means of identification:

Recommended use of the chemical: Long-acting bronchodilator used in COPD

Restrictions on use: The product should be used only for the above mentioned uses and may not be used for any other purpose than stated above.
Refer to the product insert and/or prescribing information for restrictions on use and contraindications.

Manufactured by:
Mankind Pharma Ltd.,
Unit III, Opp. Dental College, Rampur Ghat,
Teh. -Paonta Sahib (HP-173025), India.
CIN No.: U74899DL1991PLC044843
Emergency phone number: +91 1704227600

2. HAZARDS IDENTIFICATION

Classification

Globally Harmonized System, UN (GHS)

None

Labeling

Globally Harmonized System, UN (GHS)

None

Classification	
Signal Word	**None**
Precautionary Statements:	P261 Avoid breathing dust/fume/gas/mist/vapors/spray P301+P312 If swallowed: Call a poison center/doctor if you feel unwell P264 Wash thoroughly after handling P280 Wear protective gloves/protective clothing/eye protection/face protection. P273: Avoid release to the environment

Other hazards which do not result in classification: none

3. COMPOSITION / INFORMATION ON INGREDIENTS

Hazardous ingredients	CAS	Content
Formoterol Fumarate dihydrate	183814-30-4	0.00105%
Sodium Chloride	7647-14-5	< 1%
Sodium Citrate Dihydrate	6132-04-3	< 0.5%
Citric acid monohydrate	77-92-9	< 0.2%

4. FIRST-AID MEASURES

Inhalation

Remove person to fresh air, and if breathing stops, use artificial respiration. Contact physician.

Skin contact

Remove all contaminated clothing and wash skin with copious amounts of water. Contact physician if skin becomes irritated.

Eye contact

Rinse immediately with copious amounts of water. Contact a physician.

Ingestion

After swallowing: immediately make victim drink water (two glasses at most). Consult a physician.

5. FIRE-FIGHTING MEASURES

Fire extinguishing agents

Dry Chemical Foam, Carbon dioxide, Water spray or alcohol-resistant foam.

Fire/explosion hazard

None known.

Specific hazards arising from the mixture

No data available.

Personal protection

Self-contained breathing apparatus.

Special exposure hazards

Carbon oxides Nitrogen oxides (NOx) Combustible. Development of hazardous combustion gases or vapours possible in the event of fire.

6. ACCIDENTAL RELEASE MEASURES

Personal protection

Goggles, gloves, protective clothing, respiratory protection.
Remove ignition sources and provide sufficient ventilation.

Environmental precautions

Be careful not to let it flow into rivers, etc., since adverse effects on the environment are concerned.

Spillage procedure

Surround spill with absorbents and place a damp covering over the area to minimise entry of the material into the air. Add excess liquid to allow the material to enter into solution. Soak up with inert absorbent material. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Clean up remaining materials from spill with suitable absorbent.

7. HANDLING AND STORAGE

Handling
Avoid prolonged or repeated exposure. Immediately change contaminated clothing. Apply preventive skin protection. Wash hands and face after working with substance.

Fire precautions

Avoid ignition sources.
Keep away from heat/sparks/open flames/hot surfaces.

Storage facilities

Tightly closed. Dry. Keep in a well-ventilated place. Keep locked up or in an area accessible only to qualified or authorized persons.

8. EXPOSURE CONTROLS AND PERSONAL PROTECTION

Exposure limit values

Components with occupational exposure limits
Formoterol - TWA 0.05 µg/m3 (OEB 5) (Based on Internal testing as reported by MSD)

Occupational exposure controls

Appropriate engineering controls
In the manufacturing plant, provide adequate ventilation for the raw material handling. Use adequate personal protective equipment e.g. NIOSH-approved respirators, goggles or safety glasses, gloves and protective clothing. Ensure training in the handling of chemical material and use current Material Safety Data Sheets.
Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

Respiratory protection
No respiratory protection required during normal handling.

Hand protection
Gloves are not required under normal handling conditions.

Eye protection
Avoid contact with the eye. No special controls or personal protection required under conditions of intended use. In the event of a bulk spill, appropriate eye protection should be worn.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: Clear
Form: Aqueous solution
Colour: No data available
Odour: No data available
pH: No data available
Flash point: No data available
Specific gravity: No data available
n-Octanol/Water Partition Coefficient: No data available
Solubility: No data available

10. STABILITY AND REACTIVITY

Conditions to avoid

Stable under recommended storage conditions. Avoid extreme heat or cold.

Incompatible Materials: Oxidizing agents

Hazardous decomposition products

Not known.

11. TOXICOLOGICAL INFORMATION

Toxicological information refers to raw materials only. Concentrations and toxicological effects are substantially reduced in the product.

Acute toxicity -

Acute oral toxicity (LD50): - Rat - 3130 mg/kg

Acute inhalation toxicity : LC50 (Rat): 1.5 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist

Acute dermal toxicity : Remarks: No data available

Acute toxicity (other routes of administration) :
LD50 (Rat): 1,000 mg/kg -Subcutaneous

Formoterol is classified as category 4 for acute toxicity (oral).Mixture is not classifiable due to the low concentrations of the substance.

Primary Irritation (Skin/eyes)

Not classified based on available information.

Skin corrosion/irritation
Components:
Formoterol:
Species : Rabbit
Result : No skin irritation
Remarks : slight irritation

Serious eye damage/eye irritation
Not classified based on available information.
Components:
Formoterol:
Species : Rabbit
Result : No eye irritation

Respiratory or Skin sensitization – Not classifiable since the components are not classified as a skin/respiratory sensitizer.

Germ cell mutagenicity - Not classified based on available information.

Carcinogenicity - Not classified based on available information.

Reproductive toxicity - Not classified based on available information. No effects on fertility.

Specific target organ toxicity single exposure - UN GHS • Classification criteria not met

Specific target repeated exposure - UN GHS • Classification criteria not met.

Repeated dose toxicity
Components:
Formoterol:
Species : Rat
NOAEL : 0.14 mg/kg
Application Route : Inhalation
Exposure time : 13 Weeks
Target Organs : Heart
Species : Rat
LOAEL : 0.3 mg/kg
Application Route : Oral
Exposure time : 1 yr
Target Organs : Heart

12. ECOLOGICAL INFORMATION

Formoterol:

Toxicity to fish: LC50 (Oncorhynchus mykiss (rainbow trout)): > 120 mg/l (96 h)

Toxicity to daphnia and other aquatic invertebrates:
EC50 (Daphnia magna (Water flea)): > 114 mg/l (48 h)

Toxicity to algae/aquatic plants:
EC50 (Pseudokirchneriella subcapitata (green algae)): 94 mg/l (72 h)

NOEC (Pseudokirchneriella subcapitata (green algae)): 30 mg/l (72 h)

Mixture not classified for aquatic toxicity.

Persistence and degradability: Data not available

Bio accumulative potential: Data not available

Mobility in soil - Data not available

Results of PBT and vPvB assessment
This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.
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13. DISPOSAL CONSIDERATIONS

Product disposal
The method typically used is incineration.

Contaminated packaging
Contaminated, empty containers must be disposed of as chemical waste. Empty containers should be taken to an approved waste handling site for recycling or disposal

14. TRANSPORT INFORMATION

Not considered dangerous for transport

15. REGULATORY INFORMATION

CLASSIFICATION AND LABELLING

Compliance with following regulations:

- Globally Harmonized System of Classification and Labelling of Chemicals (GHS), UNECE 2003 as amended
- UN Recommendations on the Transport of Dangerous Goods, UNECE 2009

16. OTHER INFORMATION

Recommended restrictions on use

This product should be stored, handled and used in accordance with good industrial hygiene practices and in conformity with any legal regulation. The information contained herein is based on the present state of our knowledge and is intended to describe our products from the point of view of safety requirements. It should not therefore be construed as guaranteeing specific properties.

MSDS Changes

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