LUPIN LIMITED
SAFETY DATA SHEET

Section 1: Identification

Material	**Formoterol Fumarate Inhalation Solution 20 mcg/ 2 mL**
Manufacturer	Woodstock Sterile Solutions (formerly Catalent's Woodstock, IL, facility)Woodstock IL 60098, United States
Distributor	Lupin Pharmaceuticals, Inc. 111 South Calvert Street, Harborplace Tower, 21st Floor, Baltimore, Maryland 21202 United States Tel. 001-410-576-2000 Fax. 001-410-576-2221

Section 2: Hazard(s) Identification

Fire and Explosion	Expected to be non-combustible.
Health	Use of a LABA, including formoterol fumarate inhalation solution, without an inhaled corticosteroid is contraindicated in patients with asthma Formoterol fumarate inhalation solution is not indicated for the treatment of asthma.
Environment	No information is available about the potential of this product to produce adverse environmental effects.

Section 3: Composition/Information on Ingredients

Ingredients	**CAS**
Formoterol Fumarate	183814-30-4

Section 4: First-Aid Measures

Ingestion	If swallowed, call a physician immediately. Do not induce vomiting unless directed by medical personnel. Do not give anything to drink unless directed by medical personnel. Never give anything by mouth to an unconscious person. Notify medical personnel and supervisor.
Inhalation	Immediately move exposed subject to fresh air. If not breathing, give artificial respiration. If breathing is labored, administer oxygen. Immediately notify medical personnel and supervisor.
Skin Contact	Wash exposed area with soap and water and remove contaminated clothing/shoes. If irritation occurs or persists, notify medical personnel and supervisor.
Eye Contact	If easy to do, remove contact lenses, if worn. Immediately flush eyes with copious quantities of water for at least 15 minutes. If irritation occurs or persists, notify medical personnel and supervisor.

NOTES TO HEALTH PROFESSIONALS

Medical Treatment	Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information center. Protect the patient's airway and support ventilation and perfusion. Meticulously monitor and maintain, within acceptable limits, the patient's vital signs, blood gases, serum electrolytes, etc.
OVERDOSAGE	The expected signs and symptoms with overdosage of formoterol fumarate inhalation solution are those of excessive beta-adrenergic stimulation and/or occurrence or exaggeration of any of the signs and symptoms. Signs and symptoms may include angina, hypertension or hypotension, tachycardia with rates up to 200 beats/min, arrhythmias, nervousness, headache, tremor, seizures, muscle cramps, dry mouth, palpitation, nausea, dizziness, fatigue, malaise, insomnia, hyperglycemia, hypokalemia, and metabolic acidosis. As with all inhaled sympathomimetic medications, cardiac arrest and even death may be associated with an overdose of formoterol fumarate inhalation solution. Treatment of overdosage consists of discontinuation of formoterol fumarate inhalation solution together with institution of appropriate symptomatic and/or supportive therapy. The judicious use of a cardioselective beta-receptor blocker may be considered, bearing in mind that such medication can produce bronchospasm. There is insufficient evidence to determine if dialysis is beneficial for overdosage of formoterol fumarate inhalation solution. Cardiac monitoring is recommended in cases of overdosage. For additional information about overdose treatment, call a poison control center (1-800-222-1222).

Section 5: Fire-Fighting Measures

Fire and Explosion Hazards	No information identified. As product is an aqueous solution, it is not expected to be flammable or explosive.
Extinguishing Media	Use water spray (fog), foam, dry powder, or carbon dioxide, as appropriate for surrounding fire and materials.
Special Firefighting Procedures	In case of fire in the surroundings: use the appropriate extinguishing agent. Wear full protective clothing and an approved, positive pressure, self-contained breathing apparatus. Decontaminate all equipment after use
Hazardous Combustion Products	No information identified. May emit carbon monoxide, carbon dioxide, oxides of nitrogen and other nitrogen-containing compounds.

Section 6: Accidental Release Measures

Personal Precautions	If product is released or spilled, take proper precautions to minimize exposure by using appropriate personal protective equipment. Area should be adequately ventilated.
Environmental Precautions	Do not empty into drains. Avoid release to the environment
Clean-up Methods	DO NOT CAUSE MATERIAL TO BECOME AIRBORNE. For small spills, soak up material with absorbent, e.g, paper towels. For large spills, cordon off spill area and minimize the spreading of spilled material. Soak up material with absorbent. Collect spilled material, absorbent, and rinse water into suitable containers for proper disposal

in accordance with applicable waste disposal regulations. Decontaminate the area twice with an appropriate solvent.

Section 7: Handling and Storage

Handling

Follow recommendations for handling potent pharmaceutical agents (i.e, use of engineering controls and/or other personal protective equipment if needed}. Avoid contact with eyes, skin and other mucous membranes. Wash thoroughly after handling. Do not breathe vapor/mist/spray

Storage

Prior to dispensing to the patient: Store in a refrigerator, 2°C to 8°C (36°F to 46°F). Protect pouch from light and heat.

After dispensing to the patient: Store in a refrigerator at 2°C to 8°C (36°F to 46°F) and discard when drug expires or store at room temperature, 20°C to 25°C (68°F to 77°F) and discard if not used after 3 months. Protect pouch from light and heat.

- Formoterol fumarate inhalation solution should only be administered via a standard jet nebulizer connected to an air compressor with an adequate airflow and equipped with a facemask or mouthpiece.
- Vial should always be stored in the foil pouch, and only removed IMMEDIATELY before use.
- Do not take by mouth.
- Contents of any partially used container should be discarded.
- Discard the container and top after use.
- Keep out of the reach of children

Section 8: Exposure Controls/Personal Protection

Wear appropriate clothing to avoid skin contact. Wash hands and arms thoroughly after handling.

Section 9: Physical and Chemical Properties

Physical Form

Formoterol fumarate inhalation solution is supplied as a 2 mL sterile solution for nebulization in 2.1 mL low-density polyethylene unit dose vials. Each vial is overwrapped in a foil pouch and supplied in cartons as listed below. Each vial contains 2 mL of a clear, colorless solution composed of formoterol fumarate dihydrate, USP equivalent to 20 mcg of formoterol fumarate in an isotonic, sterile aqueous solution containing sodium chloride, pH adjusted to 5.0 with citric acid and sodium citrate.

Carton of 30 individually wrapped unit dose vials, **NDC 70748-261-30**
Carton of 60 individually wrapped unit dose vials, **NDC 70748-261-60**

Physical state	Liquid
Appearance	Aqueous solution
Formula	Mixture - Not applicable
Molecular mass	Mixture - Not applicable
Color	Clear
Odor	No data available
pH	No data available
Melting point	No data available
Freezing point	No data available
Boiling point	No data available
Flash point	As an aqueous solution, it is not likely to be flammable.
Relative evaporation rate (butyl acetate=1)	No data available

Flammability (solid, gas)	No data available
Vapor pressure	No data available
Relative vapor density at 20 °C	No data available
Relative density	No data available
Solubility	No data available
Log Kow	No data available
Auto-ignition temperature	As an aqueous solution, it is not likely to auto-ignite
Decomposition temperature	No data available
Viscosity, kinematic	No data available
Viscosity, dynamic	No data available
Explosion limits	No data available
Explosive properties	As an aqueous solution, it is not likely to be explosive
Oxidizing properties	No data available

Section 10: Stability and Reactivity

The product is stable and non-reactive under normal conditions of use, storage and transport.

Section 11: Toxicological Information

The carcinogenic potential of formoterol fumarate has been evaluated in 2-year drinking water and dietary studies in both rats and mice. In rats, the incidence of ovarian leiomyomas was increased at doses of 15,000 mcg/kg and above in the drinking water study and at 20,000 mcg/kg in the dietary study (AUC exposure approximately 2,300 times human exposure at the maximum recommended daily inhalation dose), but not at dietary doses up to 5,000 mcg/kg (AUC exposure approximately 570 times human exposure at the maximum recommended daily inhalation dose). In the dietary study, the incidence of benign ovarian theca-cell tumors was increased at doses of 500 mcg/kg (AUC exposure was approximately 57 times human exposure at the maximum recommended daily inhalation dose) and above. This finding was not observed in the drinking water study, nor was it seen in mice.

In mice, the incidence of adrenal subcapsular adenomas and carcinomas was increased in males at doses of 69,000 mcg/kg (AUC exposure approximately 1000 times human exposure at the maximum recommended daily inhalation dose) and above in the drinking water study, but not at doses up to 50,000 mcg/kg (AUC exposure approximately 750 times human exposure at the maximum recommended daily inhalation dose) in the dietary study. The incidence of hepatocarcinomas was increased in the dietary study at doses of 20,000 and 50,000 mcg/kg in females (AUC exposures approximately 300 and 750 times human exposure at the maximum recommended daily inhalation dose, respectively) and 50,000 mcg/kg in males, but not at doses up to 5,000 mcg/kg (AUC exposure approximately 75 times human exposure at the maximum recommended daily inhalation dose). Also, in the dietary study, the incidence of uterine leiomyomas and leiomyosarcomas was increased at doses of 2,000 mcg/kg (AUC exposure was approximately 30 times human exposure at the maximum recommended daily inhalation dose) and above. Increases in leiomyomas of the rodent female genital tract have been similarly demonstrated with other beta-agonist drugs.

Formoterol fumarate was not mutagenic or clastogenic in the following tests: mutagenicity tests in bacterial and mammalian cells, chromosomal analyses in mammalian cells, unscheduled DNA synthesis repair tests in rat hepatocytes and human fibroblasts, transformation assay in mammalian fibroblasts and micronucleus tests in mice and rats.

Reproduction studies in rats revealed no impairment of fertility at oral doses up to 3,000 mcg/kg (approximately 730 times the maximum recommended daily inhalation powder dose in humans on a mcg/m^2 basis).

Section 12: Ecological Information

No relevant studies identified.

Section 13: Disposal Considerations

Incinerate in an approved facility. Follow all federal state and local environmental regulations.

Section 14: Transport Information

Transport	Based on the available data, this mixture is not regulated as a hazardous material/dangerous good under EU ADR/RID, US DOT, Canada TOG, IATA, or IMDG.
UN number	None assigned.
UN proper shipping name	None assigned .
Transport hazard class(es) (DOT)	None assigned.
Packing group	None assigned.
Marine pollutant	Based on the available data, this mixture is not regulated as an environmental hazard or a marine pollutant.
Special transport precautions	Avoid release to the environment.
Transport in bulk according to Annex II of Marpol and the IBC Code	Not applicable

Section 15: Regulatory Information

Safety, health and environmental regulations/legislation specific for the substance or mixture	This SOS generally complies with the requirements listed under current guidelines in the US, EU and Canada. Consult your local or regional authorities for more information.
Chemical safety assessment	No chemical safety assessment has been carried out
TSCA	Drugs are exempt from TSCA.
California Proposition 65	California Proposition 65 - This product does not contain any substances known to the state of California to cause cancer, developmental and/or reproductive harm
Additional information	No additional information available.

Section 16: Other Information

Acute Tox. 2 (Inhalation:dust,mist) - Acute toxicity (inhalation:dust,mist) Category 2.
Acute Tox. 4 (Oral) - Acute toxicity (oral) Category **4.**
Care. 2 - Carcinogenicity Category 2.
Repr. 1**B** - Reproductive toxicity Category 1**B.**
Resp. Sens. 1 - Respiratory sensitization, Category 1.
STOT **RE** 1 - Specific target organ toxicity (repeated exposure) Category 1.
STOT SE 1 - Specific target organ toxicity (single exposure) Category 1.
H302 - Harmful if swallowed.
H330 - Fatal if inhaled.
H334 - May cause an allergy or asthma symptoms or breathing difficulties if inhaled.
H351 - Suspected of causing cancer.
H360D - May damage the unborn child.
H370 - Causes damage to organs.
H372 - Causes damage to organs through prolonged or repeated exposure.

Lupin shall not be held liable for any damage resulting from handling or from contact with the above product. Lupin reserves the right to revise this SDS.