LUPIN LIMITED
SAFETY DATA SHEET

Section 1: Identification

Section 1, Identification

Material	**Arformoterol Tartrate Inhalation Solution** 15 mcg / 2 mL
Manufacturer	The Ritedose Corporation 1 Technology Circle, Columbia South Carolina, 29203 - United States (USA) Tel. 001- (803) 935-4196 Fax. 001- (803) 935-4686
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

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Fire and Explosion	Expected to be non-combustible.
Health	Arformoterol tartrate inhalation solution is contraindicated in patients with a history of hypersensitivity to arformoterol, racemic formoterol or to any other components of this product. Use of a LABA, including arformoterol tartrate inhalation solution, without an inhaled cortisteroid is contraindicated in patients with asthma. Arformoterol tartrate 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

Section 3, Composition/information on ingredients

Ingredients	**CAS**
Arformoterol Tartrate	200815-49-2

Section 4: First-Aid Measures

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 associated with overdosage of arformoterol tartrate inhalation solution are those of excessive beta-adrenergic stimulation and/or occurrence or exaggeration of any of the signs. Signs and symptoms may include angina, hypertension or hypotension, tachycardia, with rates up to 200 beats/min, arrhythmias, nervousness, headache, tremor, dry mouth, palpitation, muscle cramps, nausea, dizziness, fatigue, malaise, hypokalemia, hyperglycemia, metabolic acidosis and insomnia. As with all inhaled sympathomimetic medications, cardiac arrest and even death may be associated with an overdose of arformoterol tartrate inhalation solution. Treatment of overdosage consists of discontinuation of arformoterol tartrate 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 arformoterol tartrate inhalation solution. Cardiac monitoring is recommended in cases of overdosage.

Section 5: Fire-Fighting Measures

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

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

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	Store arformoterol tartrate inhalation solution in the protective foil pouch under refrigeration at 36° to 46°F (2° to 8°C). Protect from light and excessive heat. An opened unit-dose vial should be used right away. Discard any unit-dose vial if the solution is not colorless. Unopened foil pouches of arformoterol tartrate inhalation solution can also be stored at room temperature 68° to 77°F (20° to 25°C) for up to 6 weeks. If stored at room temperature, discard if not used after 6 weeks or if past the expiration date, whichever is sooner.

Section 8: Exposure Controls/Personal Protection

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

Section 9, Physical and chemical properties

Physical Form	Arformoterol tartrate inhalation solution is supplied in a single strength (15 mcg of arformoterol, equivalent to 22 mcg of arformoterol tartrate) as 2 mL of a sterile clear colorless aqueous solution in low-density polyethylene (LDPE) unit-dose vials overwrapped in foil. Arformoterol tartrate inhalation solution is available in a shelf-carton containing 30 or 60 unit-dose vials. NDC 70748-175-30: carton of 30 individually pouched unit-dose vials. NDC 70748-175-60: carton of 60 individually pouched unit-dose vials.

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

Section 10, Stability and reactivity

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

Section 11: Toxicological Information

Section 11, Toxicological information

Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term studies were conducted in mice using oral administration and rats using inhalation administration to evaluate the carcinogenic potential of arformoterol.

In a 24-month carcinogenicity study in CD-1 mice, arformoterol caused a dose- related increase in the incidence of uterine and cervical endometrial stromal polyps and stromal cell sarcoma in female mice at oral doses of 1,000 mcg/kg and above (AUC exposure approximately 70 times adult exposure at the MRHDID).

In a 24-month carcinogenicity study in Sprague-Dawley rats, arformoterol caused a statistically significant increase in the incidence of thyroid gland c-cell adenoma and carcinoma in female rats at an inhalation dose of 200 mcg/kg (AUC exposure approximately 130 times adult exposure at the MRHDID). There were no tumor findings with an inhalation dose of 40 mcg/kg (AUC exposure approximately 55 times adult exposure at the MRHDID).

Arformoterol was not mutagenic or clastogenic in the following tests: mutagenicity tests in bacteria, chromosome aberration analyses in mammalian cells, and micronucleus test in mice.

Arformoterol had no effects on fertility and reproductive performance in rats at oral doses up to 10,000 mcg/kg (approximately 3,200 times the MRHDID in adults on a mcg/m^2 basis).

Section 12: Ecological Information

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No relevant studies identified.

Section 13: Disposal Considerations

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

Section 14: Transport Information

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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

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Safety, health and environmental regulations/legislation specific for thesubstance 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

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.