

# LUPIN LIMITED

## SAFETY DATA SHEET

### Section 1: Identification

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<b>Material</b>	<b>Atovaquone Oral Suspension USP 750 mg/5 mL</b>
<b>Manufacturer</b>	<b>Lupin Limited</b> Aurangabad - 431 210 India
<b>Distributor</b>	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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<b>Fire and Explosion</b>	Expected to be non-combustible
<b>Health</b>	Atovaquone oral suspension is contraindicated in patients who develop or have a history of hypersensitivity reactions (e.g., angioedema, bronchospasm, throat tightness, urticaria) to atovaquone or any of the components of atovaquone oral suspension.
<b>Environment</b>	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

<b>Ingredients</b>	<b>CAS</b>
Atovaquone USP	95233-18-4

### Section 4: First-Aid Measures

#### Section 4, First-aid measures

<b>Ingestion</b>	Rinse mouth. Get medical advice/attention if you feel unwell.
<b>Inhalation</b>	Move to fresh air. Call a physician if symptoms develop or persist.

<b>Skin Contact</b>	Rinse skin with water/shower. Get medical attention if irritation develops and persists.
<b>Eye Contact</b>	Rinse with water. Get medical attention if irritation develops and persists.
<b>NOTES TO HEALTH PROFESSIONALS</b>	
<b>Medical Treatment</b>	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.
<b>OVERDOSAGE</b>	In one patient who took an unspecified dose of dapstone, methemoglobinemia occurred. Rash has also been reported after overdose. There is no known antidote for atovaquone, and it is currently unknown if atovaquone is dialyzable.

## Section 5: Fire-Fighting Measures

<b>Section 5, Fire-fighting measures</b>	
<b>Fire and Explosion Hazards</b>	Assume that this product is capable of sustaining combustion.
<b>Extinguishing Media</b>	Use extinguishing media appropriate to surrounding fire conditions, such as water, fog, spray, dry chemical, regular foam, carbon dioxide.
<b>Special Firefighting Procedures</b>	For single units (packages): No special requirements needed.  For larger amounts (multiple packages/pallets) of product: Since toxic, corrosive or flammable vapors might be evolved from fires involving this product and associated packaging, self-contained breathing apparatus and full protective equipment are recommended for firefighters.
<b>Hazardous Combustion Products</b>	Hazardous combustion or decomposition products are expected when the product is exposed to fire.

## Section 6: Accidental Release Measures

<b>Section 6, Accidental release measures</b>	
<b>Personal Precautions</b>	Avoid excessive contact and contact with eyes. Wear safety goggles or shield
<b>Environmental Precautions</b>	For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems.
<b>Clean-up Methods</b>	This material is not known to possess additional hazards when spilled beyond those of other non-hazardous solids.

## Section 7: Handling and Storage

### Section 7, Handling and storage

<b>Handling</b>	No special control measures required for the normal handling of this product.
<b>Storage</b>	Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F). DO NOT FREEZE.  Dispense in a tight container as defined in USP

## 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

<b>Physical Form</b>	Atovaquone oral suspension USP (yellow colored) containing 750 mg atovaquone in 5 mL.  Bottle of 210 mL with child-resistant closure (NDC 68180-282-01)
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## Section 10: Stability and Reactivity

### Section 10, Stability and reactivity

Stable under recommended storage conditions.

## Section 11: Toxicological Information

### Section 11, Toxicological information

#### Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenicity studies in rats were negative; 24-month studies in mice (dosed with 50, 100, or 200 mg/kg/day), showed treatment-related increases in incidence of hepatocellular adenoma and hepatocellular carcinoma at all doses tested, which correlated with 1.4 to 3.6 times the average steady-state plasma concentrations in humans during acute treatment of PCP. Atovaquone was negative with or without metabolic activation in the Ames *Salmonella* mutagenicity assay, the mouse lymphoma mutagenesis assay, and the cultured human lymphocyte cytogenetic assay. No evidence of genotoxicity was observed in the *in vivo* mouse micronucleus assay.

## 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

### IATA/ICAO - Not Regulated

IATA Proper shipping Name	:	N/A
IATA UN/ID No	:	N/A
IATA Hazard Class	:	N/A
IATA Packaging Group	:	N/A
IATA Label	:	N/A

### IMDG - Not Regulated

IMDG Proper shipping Name	:	N/A
IMDG UN/ID No	:	N/A
IMDG Hazard Class	:	N/A
IMDG Flash Point	:	N/A
IMDG Label	:	N/A

### DOT - Not Regulated

DOT Proper shipping Name	:	N/A
DOT UN/ID No	:	N/A
DOT Hazard Class	:	N/A
DOT Flash Point	:	N/A
DOT Packing Group	:	N/A
DOT Label	:	N/A

## Section 15: Regulatory Information

### Section 15: Regulatory Information

This Section Contains Information relevant to compliance with other Federal and/or state laws.

## Section 16: Other Information

### Section 16, Other information

The above information is believed to be correct but does not purport to be all-inclusive and shall be used only as a guide. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.

**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.