



HETERO LABS LIMITED

"Hetero Corporate", 7-2-A2, Industrial Estates, Sanath Nagar, Hyderabad - 500 018. A.P., INDIA.
Tel : 91-40-23704923/24/25, Fax : 91-40-23704926, 23714250
e-mail : contact@heterodrugs.com URL : http://www.heterodrugs.com

SAFETY DATA SHEET

Section 1: Identification	
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GHS Product identifier	Atovaquone Oral Suspension USP, 750 mg/5mL
Trade Name	Not applicable
Other means of identification Synonyms	Not applicable
Recommended use	Medicinal Product
Manufacturer	Hetero Labs Limited Unit III, 22-110, IDA, Jeedimetla, Hyderabad-500055,
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	
Section 2, Hazard(s)identification Classified hazards Label elements	Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.
Section 3: Composition/Information on Ingredients	
Ingredients	CAS
Atovaquone (Form-A)	95233-18-4
Poloxamer	9003-11-6 or 106392-12-5
Hypromellose	9004-65-3
Benzyl alcohol	100-51-6
Xanthan gum	11138-66-2
Saccharin sodium	6155-57-3
Strawberry FL N&A Wild Type #958 K	---
Section 4: First-Aid Measures	

Inhalation	Move to fresh air. Call a physician if symptoms develop or persist.
Skin Contact	Rinse skin with water/shower. Get medical attention if irritation develops and
Eye Contact	Rinse with water. Get medical attention if irritation develops and persists.
Ingestion	Rinse mouth. Get medical advice/attention if you feel unwell
Section 5: Fire-Fighting Measures	
Section 5, Fire-fighting measures	
Suitable extinguishing media	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO ₂).
Unsuitable extinguishing media	None known.
Specific hazards arising from the chemical	During fire, gases hazardous to health may be formed.
Special protective equipment and precautions for firefighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Fire-fighting equipment/instruction	Move containers from fire area if you can do so without risk.
General fire hazards	Expected to be non-combustible
Section 6: Accidental Release Measures	
Section 6, Accidental release measures	
Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. For personal protection, see section 8 of the SDS.
Environmental precautions	Never return spills in original containers for re-use. For waste disposal, see section 13 of the SDS. Prevent further leakage or spillage if safe to do so.
Methods and materials for containment and cleaning up	Large Spills: Stop the flow of material, if this is without risk. Dike the spilled material, where this is possible. Cover with plastic sheet to prevent spreading. Absorb in vermiculite, dry sand or earth and place into containers.



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	Following product recovery, flush area with water. Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove
Section 7: Handling and Storage	
Section 7, Handling and storage	
Precautions for safe handling	Use care in handling/storage.
Conditions for safe storage, including any incompatibilities	Store at 15° to 25°C(59° to 77F). Don not freez.
Section 8: Exposure Controls/Personal Protection	
Section 8, Exposure controls/personal protection	
Components	Type
	TWA
Atovaquone (Form-A)	200mcg/m ³
Benzyl alcohol	44.2 (mg/m ³)
Individual protection measures, such as personal protective equipment	
Eye/face protection	If contact is likely, safety glasses with side shields are recommended
Hand protection	For prolonged or repeated skin contact use suitable protective gloves. The selection of gloves for a specific activity must be based on the material's properties and on possible permeation and degradation that may occur under the circumstances of use. Care must be exercised if insufficient data are available and further guidance should be sought from your local EHS department. Potential allergic reactions can occur with certain glove materials (e.g. Latex) and therefore these should be avoided. Glove selection must take into account any solvents and other hazards present.
Skin protection Other	Wear suitable protective clothing



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Respiratory protection	When workers are facing concentrations above the exposure limit they must use appropriate certified respirators
Thermal hazards	Wear appropriate thermal protective clothing, when necessary
General hygiene considerations	Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

Section 9: Physical and Chemical Properties

Section 9, Physical and chemical properties

Physical State	Liquid
Form	Suspension
Colour	yellow
Odor	Not available
Description	Atovaquone Oral Suspension USP, 750 mg/5mL Yellow homogenous suspension filled in 250 cc HDPE bottle. 210 mL PE Wad (NDC 70748- 299-01)

Section 10: Stability and Reactivity

Section 10, Stability and reactivity

Reactivity	Reacts slowly with air-Upon combustion CO and CO ₂ are formed-And formation of metallic fumes-Reacts with (some)-metals.
Chemical stability	Stable under defined conditions.

Section 11: Toxicological Information

Information on likely routes of exposure

Inhalation	Not classified.
Skin contact	Not classified



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Eye contact	Not classified		
Ingestion	Not classified		
Components			
ATOVAQUONE (CAS 95233-18-4)	Acute LD50 oral > 2000 mg/kg (Rat)	Chronic LD Oral > 500 mg/kg/day 1 Year (Rat)	Subacute LD Oral > 500 mg/kg/day 1 Year (Rat)
Poloxamer	Not available	Not available	Not available
Hypromellose	>10000 mg/kg [Rat].	Not available	Not available
Benzyl alcohol	Inhalation LC50 1000 ppm (Rat)	Oral LD50 1230 mg/kg (Rat)	Not available
Xanthan gum	Not available	Not available	Not available
Saccharin sodium	Not available	Not available	Not available
Strawberry FL N&A Wild Type #958 K	Not available	Not available	Not available

Section 12: Ecological Information

Ecotoxicity: Contains a substance which causes risk of hazardous effects to the environment.

Components	Species	Test results
ATOVAQUONE (CAS 95233-18-4)		
Aquatic		
<i>Acute</i>		
Crustacea	EC50	Water flea (Daphnia magna) 0.0035 mg/l, 48 hours Static test, OECD 202
	NOEC	Water flea (Daphnia magna) 0.0018 mg/l, 48 hours Static test
Microtox	MIC	Aspergillus flavus > 11 mcg/l
		Azotobacter chroococcum > 11 mcg/l
		Chaetomium globosum > 11 mcg/l
		Nostoc sp. > 11 mcg/l
Other	MIC	Pseudomonas acidovorans > 11 mcg/l
<i>Chronic</i>		
Crustacea	EC50	Water flea (Ceriodaphnia) 0.47 mcg/l, 8 days 7



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			day static renewal, OPPTS
	LOEC	Water flea (Ceriodaphnia)	0.16 mcg/l, 8 days
	NOEC	Water flea (Ceriodaphnia)	0.083 mcg/l, 8 days
Terrestrial			
<i>Acute</i>			
Earthworm	EC50	Manure worm (Eisenia foetida)	> 1000 mg/kg, 14 days ,
	NOEC	Manure worm (Eisenia foetida)	1000 mg/kg, 14 days Nominal
BENZYL ALCOHOL			
Aquatic			
<i>Acute</i>			
Activated Sludge	IC50	Mixed industrial/residential	2100 mg/l, 49 hours
Algae	EC50	Green algae (Scenedesmus)	640 mg/l, 96 hours
Crustacea	EC50	Water flea (Daphnia magna)	360 mg/l, 48 hours
Fish	EC50	Bluegill sunfish (Adult Lepomis macrochirus)	10 mg/l, 96 hours Static test
		Fathead minnow (Adult Pimephales)	460 mg/l, 96 hours Static test
Microtox	EC50	Microtox	63.7 mg/l, 15

Photolysis

Half-life (Photolysis-aqueous)

ATOVAQUONE 2.63 Hours Measured

Half-life (Photolysis-atmospheric)

BENZYL ALCOHOL 2 Days Estimated

Biodegradability

Percent degradation (Aerobic biodegradation-soil)

ATOVAQUONE 75 %, 1 Day, Soil

Percent degradation (Anaerobic biodegradation)

BENZYL ALCOHOL 100 %, 14 days Serum Bottle,
 Anaerobic sludge

Bio accumulative potential No data available for this product.

Partition coefficient n-octanol / water (log Kow)



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ATOVAQUONE	5.31
BENZYL ALCOHOL	1.1
Bio concentration factor (BCF)	
BENZYL ALCOHOL	4 Estimated
Mobility in soil	
Adsorption	
Sludge/biomass distribution coefficient - log Kd	
ATOVAQUONE	3.91 - 4.31 Calculated
Soil/sediment sorption - log Koc	
ATOVAQUONE	4.18 - 4.58 Measured
BENZYL ALCOHOL	< 0.7 Measured
Mobility in general	
Volatility	
Henry's law	
BENZYL ALCOHOL	0 atm m ³ /mol, 25 C Estimated
Other adverse effects	Not available.
Section 13: Disposal Considerations	
Waste treatment methods	
Disposal instructions	Collect and reclaim or dispose in sealed containers at licensed waste
Local disposal regulations	No data available
Hazardous waste code	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
Waste from residues I unused	Dispose of in accordance with local regulations. Empty containers or liners may retain some Product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
Contaminated packaging	Empty containers should be taken to an approved waste handling site for recycling or disposal.



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Section 14: Transport Information

DOT	
UN-Number Proper shipping name Hazard class Reportable quantity Description Emergency response guide Number	Not applicable
IATA	
UN-Number Proper shipping name Hazard class Description	Not applicable
IMDG	
UN-Number Proper shipping name Hazard class Reportable quantity Description Emergency response guide Number	Not applicable

Section 15: Regulatory Information

U.S State regulations
California Proposition 65: This product does not content any proposition 65 chemicals

Section 16: Other Information

Section 16,
Other information
Issue Date : 25-05-2021
Version : 00
Further information
Revision date: New issue
Revision note: New issue

The information and recommendations in this safety data sheet 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. 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.

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

