

SAFETY DATA SHEET

Section 1: Identification				
Material	Aripiprazole Oral Solution 1 mg/ml			
Recommended use	Human Pharmaceutical.			
Manufacturer	Hetero Labs Limited, Unit-III			
	22-110, IDA, Unit III, Jeedimetla,			
	Hyderabad-500055, India.			
Distributor	Camber Pharmaceuticals, Inc., Piscataway, NJ 08854			
	Section 2: Hazard(s) Identification			
Hazard statements	Causes serious eye irritation. Wash thoroughly after handling. Do not eat, drink or smoke when using this product. Wear eye protection / face protection.			
Section	3: Composition/Information on Ingredients			
Ingredients	CAS			
Aripiprazole	129722-12-9			
Edetate Disodium	6381-92-6			
Fructose	57-48-7			
Glycerine	56-81-5			
Malic acid	6915-15-7			
Methylparaben	99-76-3			
Orange flavour	NA			
Propylene glycol	57-55-6			
Propylparaben	94-13-3			
Sodium Hydroxide	1310-73-2			
Sucrose	57-50-1			
Purified water	7732-18-5			
Sect	ion 4: First-Aid Measures			
Eye Contact	Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Get medical attention.			
Skin Contact	Wash off immediately with plenty of water for at least 15 minutes. If skin irritation persists, call a physician.			
Inhalation	Remove to fresh air. If not breathing, give artificial respiration. Get medical attention if symptoms occur.			
General information	Immediately remove any clothing soiled by the product. In case of irregular breathing or respiratory arrest provide artificial respiration.			
Notes to Physician	Treat symptomatically			



Section 5: Fire-Fighting Measures					
Suitable Extinguishing Media	Water spray, carbon dioxide (CO2), dry chemical, alcohol-				
	resistant foam.				
Unsuitable Extinguishing	No information available				
Media					
Flash Point	No information available				
Method -	No information available				
Autoignition Temperature	No information available				
Sec	Section 6: Accidental Release Measures				
Personal Precautions	Ensure adequate ventilation. Use personal protective equipment as required. Avoid dust formation.				
Environmental Precautions	Should not be released into the environment				
Methods for Containment and	Sweep up and shovel into suitable containers for disposal. Keep in				
Clean Up	suitable, closed containers for disposal				
	Section 7: Handling and Storage				
Handling	Do not get in eyes, on skin, or on clothing. Avoid dust formation.				
Storage	Store at 25°C (77°F); excursions permitted between 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature].				
Section 8	8: Exposure Controls/Personal Protection				
Exposure Guidelines	This product does not contain any hazardous materials with occupational exposure limits established by the region-specific regulatory bodies				
Engineering Measures	Ensure adequate ventilation, especially in confined areas.				
Personal Protective Equipment					
Hygiene Measures	Handle in accordance with good industrial hygiene and safety practice.				
G					
	n 9: Physical and Chemical Properties				
Physical Form Description	Solution Arinimazala Oral Salution (1 mg/ml.) is supplied in shild resistant.				
Description	Aripiprazole Oral Solution (1 mg/mL) is supplied in child-resistant bottles along with a calibrated oral dosing cup. Aripiprazole Oral Solution is available as follows:				
	150 mL Bottle NDC 31722-684-15				



Section 10: Stability and Reactivity			
Reactive Hazard	None known, based on information available		
Stability	Stable under normal conditions.		

Section 11: Toxicological Information

Acute toxicity:

Product is toxic on ingestion. LD50 of Aripiprazole is reported as 196 mg/kg (rat, oral).

Carcinogenesis: This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.

Mutagenesis: 2,3-DCPP was clast genic in the in vitro chromosomal aberration assay in Chinese hamster lung (CHL) cells with and without metabolic activation.

Impairment of Fertility: No effect on fertility in female and male rats were observed.

Section 12: Ecological Information

Ecotoxicity

Do not empty into drains.

Persistence and Degradability Insoluble in water

Bioaccumulation/ **Accumulation** No information available.

Mobility Is not likely mobile in the environment due its low water solubility.

Section 13: Disposal Considerations

Waste Disposal Methods	Chemical waste generators must determine whether a
	discarded chemical is classified as a hazardous waste.
	Chemical waste generators must also consult local,
	regional, and national hazardous waste regulations to
	ensure complete and accurate classification.

Section 14: Transport Information

DOT	Not regulated	
TDG	Not regulated	
IATA	Not regulated	
IMDG/IMO	Not regulated	

Section 15: Regulatory Information

United States of America Inventory

Component	CAS No	TSCA	TSCA Inventory notification -Active-Inactive	TSCA - EPA Regulatory Flags
Aripiprazole	129722- 12-9	-	-	-



U.S. Federal Regulations

SARA 313 Not applicable

SARA 311/312 Hazard Categories See section 2 for more information

CWA (Clean Water Act)

Clean Air Act

Not applicable

Not applicable

OSHA - Occupational Safety and

Health Administration

Not applicable

CERCLA Not applicable

California Proposition 65 This product does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know

Regulations Not applicable

FDA: Aripiprazole is an approved prescription medication.

Section 16: Other Information

Issue Date: 18-05-2023

Version: 00

Further information

Revision date: NA

Revision note: NA

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.

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