



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
Section 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 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) Not applicable

Clean Air Act 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.

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.