



SAFETY DATA SHEET

Section 1: Identification	
Material	Fluphenazine Hydrochloride Tablets USP 1 mg, 2.5 mg, 5 mg, 10 mg
Recommended use	Management of manifestations of psychotic disorders.
Manufacturer	Hetero Labs Limited, 22-110, IDA, Unit III, Jeedimetla, Hyderabad-500055, India.
Distributor	Camber Pharmaceuticals, Inc. , Piscataway, NJ 08854
Section 2: Hazard(s) Identification	
Potential Health Effects	Inhalation: Not expected to be hazardous in final pharmaceutical form. Eye Contact: Not expected to be hazardous in final pharmaceutical form. Skin Contact: Not expected to be hazardous in final pharmaceutical form. Ingestion: Health injuries are not known or expected under normal use. Exposures above clinical dosage could result in adverse effects. Minor occupational exposures are not expected to be harmful. Other: None.
Effects of Overexposure	The potential for exposure is reduced in finished pharmaceutical form.
Section 3: Composition/Information on Ingredients	
Ingredients	CAS
Fluphenazine Hydrochloride	146-56-5
Microcrystalline Cellulose	9004-34-6
Croscarmellose Sodium	74811-65-7
Pregelatinized Starch	9005-25-8
Magnesium Stearate	557-04-0
Opadry White	NA



Opadry Yellow	NA
Opadry Green	NA
Opadry Red	NA
Section 4: First-Aid Measures	
Inhalation	IF INHALED: Remove to fresh air and keep at rest in a position comfortable for breathing. Get medical attention immediately if symptoms occur.
Skin contact	Wash off immediately with soap and plenty of water. If skin irritation or rash occurs: Get medical advice/attention.
Eye contact	In case of eye contact, immediately flush eyes with plenty of water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.
Ingestion	Do not induce vomiting without medical advice. Rinse mouth thoroughly with water. Get medical attention if symptoms occur.
Section 5: Fire-Fighting Measures	
Extinguishing media	
Suitable extinguishing agents	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Water spray, alcohol-resistant foam, carbon dioxide, dry chemical powder or appropriate foam.
Fire hazard	Not flammable
Reactivity	Hazardous reactions will not occur under normal conditions.
Hazardous combustion products	Carbon oxides
Section 6: Accidental Release Measures	
Personal Precautions	Ensure adequate ventilation. Use personal protective equipment as required. Evacuate personnel to safe areas. Eliminate all ignition sources if safe to do so.
Environmental Precautions	Do not flush into surface water or sanitary sewer system. Should not be released into the environment.
Methods and Material for Containment and Cleaning Up	Prevent further leakage or spillage if safe to do so. Use appropriate personal protective equipment (PPE). Carefully shovel or sweep up spilled material and place in suitable container. Avoid generating dust. For spills: Soak



	<p>5 mg tablets are light green to green color, round, biconvex film-coated tablet debossed "H" on one side and "F15" on other side They are supplied in</p> <p>Bottles of 100 NDC 31722-386-01</p> <p>Bottles of 500 NDC 31722-386-05</p> <p>10 mg tablets are light red to red color, round, biconvex film-coated tablet debossed "H" on one side and "F16" on other side They are supplied in</p> <p>Bottles of 100 NDC 31722-387-01</p> <p>Bottles of 500 NDC 31722-387-05</p>
--	--

Section 10: Stability and Reactivity

Reactivity	Hazardous reactions will not occur under normal conditions.
Chemical stability	Stable under normal conditions
Possibility of hazardous reactions	None under normal processing.
Conditions to avoid	Extremes of temperature and direct sunlight.
Incompatible materials	Strong oxidizing agents, strong acids, and strong bases.
Hazardous decomposition products	Decomposition will not occur under normal conditions

Section 11: Toxicological Information

Information on Toxicological Effects General Information:	
Acute toxicity:	
Skin	Irritant to skin and mucous membranes
Eye	Strong irritant with the danger of severe eye injury
Sensitization:	Sensitization possible through skin contact
Additional toxicological information:	
Interactive effects	No interactive effects between components are known
Carcinogenic categories	
IARC (International Agency for Research on Cancer)	Substance is not listed
NTP (National Toxicology Program)	Substance is not listed
OSHA-Ca (Occupational Safety & Health Administration)	Substance is not listed



Alternative sources for toxicological information	No non-standard sources for toxicological information where used.
Section 12: Ecological Information	
Toxicity:	
Germ cell mutagenicity	Based on available data, the classification criteria are not met.
Carcinogenicity	Based on available data, the classification criteria are not met.
Reproductive toxicity	Contains a known or suspected reproductive toxin.
STOT - single exposure	Based on available data, the classification criteria are not met.
Section 13: Disposal Considerations	
Waste Treatment Methods:	Must not be disposed of together with household garbage. Do not allow product to reach sewage system.
Uncleaned packagings	Disposal must be made according to official regulations
Section 14: Transport Information	
DOT, IMDG, IATA	Not regulated for transport of dangerous goods.
Section 15: Regulatory Information	
DEA: Not Available. FDA: Fluphenazine Hydrochloride Tablets, USP is an approved prescription medication. Inventory Status: This material is not listed on the US TSCA Inventory.	
Section 16: Other Information	
Issue Date : 24-03-2026	
Version: 00	
Further information	
Revision date: NA	
Revision note: NA	
<p>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.</p>	
<p>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.</p>	