



SAFETY DATA SHEET

Section 1: Identification	
Material	Olanzapine for Injection
Manufacturer	Aspiro Pharma Limited, Sy. No. 321, Biotech Park, Phase-III, Karkapatla Village, Markook Mandal, Telangana (S), Siddipet (Dist.)-502281, India.
Distributor	Camber Pharmaceuticals, Inc., Piscataway, NJ 08854
Section 2: Hazard(s) Identification	
Hazard statements	May form combustible dust concentrations in air. Harmful if swallowed. May cause an allergic skin reaction. Causes serious eye damage.
Precautionary Statements	Avoid breathing vapors, mist, or spray. Wash hands, forearms, and other exposed areas thoroughly after handling. Do not eat, drink or smoke when using this product. Contaminated work clothing must not be allowed out of the workplace. Wear protective gloves, protective clothing, and eye protection. If swallowed: Call a poison center or doctor if you feel unwell. If on skin: Wash with plenty of water If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a poison center or doctor Rinse mouth. If skin irritation or rash occurs: Get medical advice/attention. Take off contaminated clothing and wash it before reuse. Dispose of contents/container in accordance with local, regional, national, and international regulations.
Other Hazards	Exposure may aggravate those with pre-existing eye, skin, or respiratory conditions. Therapeutic use has resulted in the following adverse effects: sleepiness, weight gain, increases in serum prolactin, dizziness, weakness, restlessness, increase appetite, swelling of hands and feet, decreased blood pressure when standing, dry mouth and constipation Overdose of the drug has resulted in changes in heart rate and rhythm, slurred speech, reduced level of consciousness ranging from sedation to coma.



Section 3: Composition/Information on Ingredients	
Ingredients	CAS
Lactose, monohydrate	10039-26-6
Olanzapine	132539-06-1
Tartaric acid	87-69-4
Hydrochloric acid	7647-01-0
Sodium Hydroxide	1310-73-2
Water for Injection	7732-18-5
Section 4: First-Aid Measures	
Inhalation	Using proper respiratory protection, move the exposed person to fresh air at once. Encourage exposed person to cough, spit out, and blow nose to remove dust. Immediately call a poison center, physician, or emergency medical service.
Skin Contact	Remove contaminated clothing. Drench affected area with water for at least 15 minutes. Obtain medical attention if irritation develops or persists.
Eye Contact	Rinse cautiously with water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention.
General information	In the event of accidental injection, immediately call a poison center or seek medical advice. Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).
Section 5: Fire-Fighting Measures	
Extinguishing Media (Suitable)	Dry chemical, carbon dioxide, water spray, fog.
Unsuitable Extinguishing Media	Do not use a heavy water stream. Use of heavy stream of water may spread fire.
Advice for Firefighters	
Precautionary Measures Fire	Exercise caution when fighting any chemical fire.
Firefighting Instructions	Use water spray or fog for cooling exposed containers
Protection During Firefighting	Do not enter fire area without proper protective equipment, including respiratory protection.
Other Information	Risk of dust explosion.



Section 6: Accidental Release Measures	
Personal Precautions, Protective Equipment and Emergency Procedures	Avoid breathing dust. Do not get in eyes, on skin, or on clothing. Avoid generating dust. Remove ignition sources. Keep away from heat, hot surfaces, sparks, open flames, and other ignition sources. No smoking.
General Measures	
For Non-emergency Personnel	
Protective Equipment	Use appropriate personal protection equipment (PPE).
Emergency Procedures	Evacuate unnecessary personnel.
For Emergency Responders	
Protective Equipment	Equip cleanup crew with proper protection.
Emergency Procedures	Upon arrival at the scene, a first responder is expected to recognize the presence of dangerous goods, protect oneself and the public, secure the area, and call for the assistance of trained personnel as soon as conditions permit
Environmental Precautions	Prevent entry to sewers and public waters.
Methods and Material for Containment and Cleaning Up For Containment	Contain solid spills with appropriate barriers and prevent migration and entry into sewers or streams. Avoid generation of dust during clean-up of spills.
Methods for Cleaning Up	Clean up spills immediately and dispose of waste safely. Contact competent authorities after a spill. Use explosion proof vacuum during cleanup, with appropriate filter. Do not mix with other materials. Vacuum clean-up is preferred. If sweeping is required use a dust suppressant. Use only non-sparking tools.
Section 7: Handling and Storage	
Precautions for Safe Handling Additional Hazards When Processed	Use only as directed by the information identified in the package insert. Accumulation and dispersion of dust with an ignition source can cause a combustible dust explosion. Keep dust levels to a minimum and follow applicable regulations.
Precautions for Safe Handling	Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Avoid breathing dust. Handle empty containers with care because they may still present a hazard. Do not get in eyes, on skin, or on clothing. Avoid creating or spreading dust. Keep away from heat, sparks, open flames, hot surfaces. – No smoking.
Hygiene Measures	Handle in accordance with good industrial hygiene and safety procedures.



Section 10: Stability and Reactivity	
Reactivity	Hazardous reactions will not occur under normal conditions
Chemical Stability	Stable under recommended handling and storage conditions
Possibility of Hazardous Reactions	Hazardous polymerization will not occur.
Conditions to Avoid	Direct sunlight, extremely high or low temperatures, and incompatible materials. Sparks, heat, open flame and other sources of ignition.
Incompatible Materials	Strong oxidizers.
Hazardous Decomposition Products	Thermal decomposition generates: Carbon oxides. Nitrogen oxides. Sulfur oxides.
Section 11: Toxicological Information	
Information On Toxicological Effects	
Acute Toxicity: Oral: Harmful if swallowed.	
Olanzapine for Injection	
ATE (Oral)	636.94 mg/kg body weight
Olanzapine (132539-06-1)	
ATE (Oral)	100.00 mg/kg body weight
(+)-Tartaric acid (87-69-4)	
LD50 Oral Rat	10000 - 16000 mg/kg
<p>Skin Corrosion/Irritation: Not classified (pH: Neutral)</p> <p>Serious Eye Damage/Irritation: Causes serious eye damage. (pH: Neutral)</p> <p>Respiratory or Skin Sensitization: May cause an allergic skin reaction.</p> <p>Germ Cell Mutagenicity: Not classified</p> <p>Carcinogenicity: Not classified</p> <p>Reproductive Toxicity: Not classified</p> <p>US FDA Pharmaceutical Pregnancy Category C: Animal reproduction studies have shown an adverse effect on the fetus and there are no adequate and well-controlled studies in humans, but potential benefits may warrant use of the drug in pregnant women despite potential risks.</p> <p>Specific Target Organ Toxicity (Single Exposure): Not classified</p> <p>Specific Target Organ Toxicity (Repeated Exposure): Not classified</p> <p>Aspiration Hazard: Not classified</p>	



Symptoms/Injuries After Inhalation: Dust may be harmful or cause irritation.

Symptoms/Injuries After Skin Contact: May cause an allergic skin reaction.

Symptoms/Injuries After Eye Contact: Contact causes severe irritation with redness and swelling of the conjunctiva.

Symptoms/Injuries After Ingestion: This material is harmful orally and can cause adverse health effects or death in significant amounts.

Chronic Symptoms: None expected under normal conditions of use.

Section 12: Ecological Information

Toxicity Ecology - General: Not classified.

Persistence and Degradability: Not established

Bioaccumulative Potential: Not established

Mobility in Soil: No additional information available

Other Adverse Effects

Other Information: Avoid release to the environment

Section 13: Disposal Considerations

Waste treatment methods

Waste Disposal Recommendations: Dispose of contents/container in accordance with local, regional, national, and international regulations.

Additional Information: Container may remain hazardous when empty. Continue to observe all precautions.

Ecology – Waste Materials: Avoid release to the environment.

Section 14: Transport Information

In Accordance with DOT Not regulated for transport

In Accordance with IMDG Not regulated for transport

In Accordance with IATA Not regulated for transport



Section 15: Regulatory Information

US Federal Regulations

Olanzapine for Injection

SARA Section 311/312 Hazard
Classes

Delayed (chronic) health hazard
Immediate (acute) health hazard

(+)-Tartaric acid (87-69-4)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

US State Regulations Neither this product nor its chemical components appear on any US state lists

Section 16: Other Information

Issue Date: 18-05-2023

Version: 00

Further information

Revision date: New issue

Revision note: New issue

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