

SAFETY DATA SHEET

Olanzapine for Injection

1. IDENTIFICATION

Product identifier: Olanzapine for Injection

Product Codes:

Supplier Name and Address: PAI Pharma
1700 Perimeter Road
Greenville, SC 29605

Telephone number: (864) 277-7282

Emergency phone number: CHEMTREC 800-424-9300

Recommended use: Human drug – antipsychotic

Restrictions on use: Use only as directed. Prescription Only

2. HAZARD(S) IDENTIFICATION

Classification:

Physical	Health
Not hazardous	Acute Oral Toxicity Category 4 Eye Damage Category 1 Skin Sensitization Category

Label Elements:
DANGER!



Hazard statement(s)

Harmful if swallowed.
Causes serious eye damage.
May cause an allergic skin reaction.

Precautionary statement(s)

Avoid breathing dust. Wash hands thoroughly after handling. Do not eat, drink or smoke when using this product. Contaminated clothing must not be allowed out of the workplace.

Precautionary statement(s)

Wear eye protection, protective clothing and gloves.
IF SWALLOWED: Call a poison center if you feel unwell.
Rinse mouth.
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.
IF ON SKIN: Wash with plenty of soap and water. If skin irritation or rash occurs: Get medical attention. Take off contaminated clothing and wash it before reuse.
Store locked up.
Dispose in accordance with local and national regulations.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical name	CAS No.	Amount (w/w%)
Olanzapine	132539-06-1	15-20%
Tartaric acid	87-69-4	5-10%
Non-Hazardous Ingredients	Mixture	Balance

The exact percentage (concentration) of composition has been withheld as a trade secret.

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4. FIRST-AID MEASURES

Inhalation: Remove person to fresh air. If irritation occurs, get medical attention.

Skin contact: Wash skin with soap and water. If irritation or rash develop, get medical attention. Launder contaminated clothing before reuse.

Eye contact: Immediately flush eyes with water while lifting the upper and lower lids for at least 15 minutes. Remove contact lenses, if present and easy to do after 5 minutes, then continue rinsing. Get immediate medical attention.

Ingestion: In the case of unintentional ingestion or overdosage, rinse mouth with water. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to a person who is unconscious or convulsing. Get medical attention.

Most important symptoms/effects, acute and delayed: Causes severe eye irritation with possible permanent eye damage. May cause an allergic skin reaction. Swallowing may cause heart rate and rhythm, slurred speech, reduced level of consciousness ranging from sedation to coma, convulsion, and muscle rigidity. May cause blood damage.

Indication of immediate medical attention and special treatment, if necessary: Immediate medical attention is required for eye contact. Medical attention is recommended for unintended ingestion.

5. FIRE-FIGHTING MEASURES

Extinguishing media: Use water spray, carbon dioxide, dry chemical or foam to extinguish a fire.

Specific hazards arising from the chemical: This product is not a fire hazard but may burn under fire conditions.

Special protective equipment and precautions for fire-fighters: Firefighters should wear positive pressure self-contained breathing apparatus and full protective clothing for all fires involving chemicals. Cool fire exposed containers with water.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment, and emergency procedures: Wear appropriate protective clothing and equipment as described in Section 8.

Environmental Precautions: Prevent spill from entering sewers and water courses. Report releases as required by local and national authorities.

Methods and materials for containment and cleaning up: Carefully collect solid material, avoiding the creating of airborne dust. Do not use a vacuum unless explosion-proof. Contain and collect liquid with an inert absorbent material. Place in appropriate container for disposal. Clean area thoroughly.



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7. HANDLING AND STORAGE

Precautions for safe handling: Avoid the generation of dust. Do not get in eyes. Avoid contact with skin and clothing. Wash thoroughly with soap and water after handling.

Conditions for safe storage, including any incompatibilities: Store as indicated on product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure guidelines:

Olanzapine	STEG (15 minutes) 114 ug/m ³ ; TWA (8 hr) 50 ug/m ³ Supplier recommended
Tartaric acid	None Established
Non-Hazardous Ingredients	None Established

Appropriate engineering controls: Use with adequate general or local exhaust ventilation to keep exposures below occupational exposure limits and to minimize exposure levels.

Individual protection measures:

Respiratory protection: None needed under normal use conditions. If exposure limits are exceeded, a NIOSH approved particulate respirator is recommended. Selection of respiratory protection depends on the contaminant type, form and concentration. Select in accordance with OSHA 1910.134 and good Industrial Hygiene practice.

Skin protection: None required for normal use. Impervious gloves recommended for manufacturing operations and if skin contact is possible.

Eye protection: None required for normal use. Chemical safety goggles recommended if eye contact is possible.

Other: Protective clothing recommended for manufacturing operations and if skin contact is possible.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Solid	Color: Yellow
Odor: Odorless	pH: No data available
Melting point/freezing point: Not determined	Boiling Point: Not determined
Flash point: Not applicable	Particle Characteristics: No data available
Flammability: Not flammable	VOC: Not determined
Flammable limits: LEL: Not applicable	UEL: Not applicable
Vapor pressure: Not applicable	Relative Vapor density: Not applicable
Relative density: No data available	Solubility(ies): Soluble in water
Partition coefficient: n-octanol/water: Not available	Auto-ignition temperature: Not available
Decomposition temperature: Not available	Kinematic Viscosity: Not applicable

10. STABILITY AND REACTIVITY

Reactivity: Not reactive under normal conditions of use.

Chemical stability: Stable.



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Possibility of hazardous reactions: None known.

Conditions to avoid: None known.

Incompatible materials: Avoid oxidizing agents.

Hazardous decomposition products: Thermal decomposition may yield carbon oxides, nitrogen oxides, sulfur oxides.

11. TOXICOLOGICAL INFORMATION

Acute effects of exposure:

Inhalation: Inhalation of dust may cause irritation of the mucous membranes and upper respiratory tract and symptoms similar to ingestion.

Ingestion: Swallowing may cause heart rate and rhythm, slurred speech, reduced level of consciousness ranging from sedation to coma, convulsion, and muscle rigidity. May cause blood damage.

Skin contact: May cause mild irritation. May cause an allergic skin reaction.

Eye contact: Causes severe eye irritation and possible eye damage.

Chronic Effects: None known.

Sensitization: May cause an allergic skin reaction. Olanzapine did not cause sensitization in laboratory animals, however, confirmed cases of allergic contact dermatitis have been reported. Symptoms have included rash with redness, swelling, and scaling of the affected skin areas.

Germ Cell Mutagenicity: None of the components have been shown to cause germ cell mutagenicity. Olanzapine was not mutagenic in in-vitro and in vivo tests.

Reproductive Toxicity: Decreased mating activity due to sedation was observed in animal studies with olanzapine. Decreased fertility, abnormal reproductive cycles, and reproductive tissue changes can be linked to elevations of prolactin levels. The clinical effects of such elevations are unknown for humans. Embryo and fetal toxicity occurred only at maternally toxic doses.

Carcinogenicity: None of the components are listed as carcinogens or suspected carcinogens by IARC, NTP, ACGIH or OSHA. Based on results of studies in rats and mice, it was concluded that olanzapine is not carcinogenic.

Acute Toxicity Values: Acute Oral Toxicity Estimate (ATE) calculated: >5000 mg/kg

Olanzapine: LD50 oral rat 177 mg/kg

Tartaric acid: LD50 oral rat >5000 mg/kg

12. ECOLOGICAL INFORMATION

Environmental properties have not been fully evaluated. Releases to the environment should be avoided.

Ecotoxicity values: No data available.

Persistence and degradability: No data available.

Bioaccumulative potential: No data available.

Mobility in soil: No data is available.

Other adverse effects: None known.

13. DISPOSAL CONSIDERATIONS

Dispose in accordance with all local, state and federal regulations.



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14. TRANSPORT INFORMATION

	UN Number	Proper shipping name	Hazard Class	Packing Group	Environmental Hazard
DOT		Not Regulated			
TDG		Not Regulated			
IMDG		Not Regulated			
IATA		Not Regulated			

Transport in bulk according to IMO instruments: Not applicable – product is transported only in packaged form.

Special precautions: None known.

15. REGULATORY INFORMATION

Safety, health, and environmental regulations specific for the product in question.

CERCLA: This product is not subject to CERCLA release reporting. Many states have more stringent release reporting requirements. Report spills as required under federal, state and local regulations.

SARA Hazard Category (311/312): Refer to Section 2 for the OSHA Hazard Classification.

EPA SARA 313: This product contains the following chemicals regulated under SARA Title III, section 313:
None

EPA TSCA Inventory: This product is a drug and not subject to TSCA.

California Proposition 65: Olanzapine is a benzodiazepine. Benzodiazepines are listed as a developmental toxins.

CANADA:

Canadian CEPA: This product is a drug and not subject to CEPA regulations.

16. OTHER INFORMATION

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SDS Revision History: New SDS

Disclaimer: The information provided on this SDS is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guide for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered as a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other material or in any process, unless specified in the text.