

Olanzapine for Injection

Safety Data Sheet

According To Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules And Regulations
Revision Date: 08/04/2015 Date of issue: 08/04/2015

Version: 1.0

SECTION 1: IDENTIFICATION

1.1. Product Identifier

Product Form: Mixture

Product Name: Olanzapine for Injection

Product Code: (NDC) 0517-0955-01

1.2. Intended Use of the Product

Use of the substance/mixture: Injectable Antipsychotic

1.3. Name, Address, and Telephone of the Responsible Party

Company

PharmaForce, Inc.
6610 New Albany Road East
New Albany, OH 43054
T 614-436-2222
www.pharmaforceinc.com

Distributor

American Regent, Inc.
One Luitpold Drive
P.O. Box 9001
Shirley, NY 11967
1-800-645-1706
www.luitpold.com

1.4. Emergency Telephone Number

Emergency Number : 1-800-424-9300 CHEMTREC

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the Substance or Mixture

Classification (GHS-US)

Comb. Dust H232
Acute Tox. 4 (Oral) H302
Eye Dam. 1 H318
Skin Sens. 1 H317

Full text of H-phrases: see section 16

2.2. Label Elements

GHS-US Labeling

Hazard Pictograms (GHS-US)



Signal Word (GHS-US)

: Danger

Hazard Statements (GHS-US)

: H232 - May form combustible dust concentrations in air.
H302 - Harmful if swallowed.
H317 - May cause an allergic skin reaction.
H318 - Causes serious eye damage.

Precautionary Statements (GHS-US)

: P261 - Avoid breathing vapors, mist, or spray.
P264 - Wash hands, forearms, and other exposed areas thoroughly after handling.
P270 - Do not eat, drink or smoke when using this product.
P272 - Contaminated work clothing must not be allowed out of the workplace.
P280 - Wear protective gloves, protective clothing, and eye protection.
P301+P312 - If swallowed: Call a poison center or doctor if you feel unwell.
P302+P352 - If on skin: Wash with plenty of water.
P305+P351+P338 - If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310 - Immediately call a poison center or doctor.
P321 - Specific treatment (see section 4 on this SDS).
P330 - Rinse mouth.
P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.
P362+P364 - Take off contaminated clothing and wash it before reuse.
P501 - Dispose of contents/container in accordance with local, regional, national, and international regulations.

2.3. 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.

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Overdose of the drug has resulted in changes in heart rate and rhythm, slurred speech, reduced level of consciousness ranging from sedation to coma.

2.4. Unknown Acute Toxicity (GHS-US)

No data available

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substance

Not applicable

3.2. Mixture

Name	Product Identifier	%	Classification (GHS-US)
Lactose, monohydrate	(CAS No) 64044-51-5	78.7	Comb. Dust
Olanzapine	(CAS No) 132539-06-1	15.7	Acute Tox. 3 (Oral), H301 Eye Irrit. 2A, H319 Skin Sens. 1, H317 STOT SE 3, H336
(+)-Tartaric acid	(CAS No) 87-69-4	5.6	Skin Irrit. 2, H315 Eye Dam. 1, H318

Full text of H-phrases: see section 16

SECTION 4: FIRST AID MEASURES

4.1. Description of First Aid Measures

First-aid Measures General: 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).

First-aid Measures After 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.

First-aid Measures After Skin Contact: Remove contaminated clothing. Drench affected area with water for at least 15 minutes. Obtain medical attention if irritation develops or persists.

First-aid Measures After 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.

First-aid Measures After Ingestion: Rinse mouth. Do NOT induce vomiting. Obtain medical attention.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms/Injuries: Exposure to large amounts of dust may cause irritation. Causes serious eye damage. Harmful if swallowed. Skin sensitization.

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: Causes severe irritation which will progress to chemical burns.

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.

4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed

If exposed or concerned, get medical advice and attention. If medical advice is needed, have product container or label at hand.

SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing Media

Suitable Extinguishing Media: 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.

5.2. Special Hazards Arising From the Substance or Mixture

Fire Hazard: Combustible Dust.

Explosion Hazard: Dust explosion hazard in air.

Reactivity: Hazardous reactions will not occur under normal conditions.

5.3. 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.

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SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures

General Measures: 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.

6.1.1. For Non-emergency Personnel

Protective Equipment: Use appropriate personal protection equipment (PPE).

Emergency Procedures: Evacuate unnecessary personnel.

6.1.2. 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.

6.2. Environmental Precautions

Prevent entry to sewers and public waters.

6.3. 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.

6.4. Reference to Other Sections

See Section 8, Exposure Controls and Personal Protection. See Section 13, Disposal Considerations.

SECTION 7: HANDLING AND STORAGE

7.1. 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.

7.2. Conditions for Safe Storage, Including Any Incompatibilities

Technical Measures: Comply with applicable regulations. Avoid creating or spreading dust. Use explosion-proof electrical, ventilating, lighting equipment. Proper grounding procedures to avoid static electricity should be followed.

Storage Conditions: Keep container closed when not in use. Store in a dry, cool place. Keep/Store away from direct sunlight, extremely high or low temperatures and incompatible materials.

Incompatible Products: Strong oxidizers.

7.3. Specific End Use(s) Injectable Antipsychotic

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control Parameters

For substances listed in section 3 that are not listed here, there are no established exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), NIOSH (REL), or OSHA (PEL).

8.2. Exposure Controls

Appropriate Engineering Controls : Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure. Ensure adequate ventilation, especially in confined areas. Ensure all national/local regulations are observed. Proper grounding procedures to avoid static electricity should be followed. Use explosion-proof equipment. Use local exhaust or general dilution ventilation or other suppression methods to maintain dust levels below exposure limits. Power equipment should be equipped with proper dust collection devices. It is recommended that all dust control equipment such as local exhaust ventilation and material transport systems involved in handling of this product contain explosion relief vents or an explosion suppression system or an oxygen-deficient environment.

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Personal Protective Equipment : Gloves. Protective clothing. Protective goggles. Dust formation: dust mask.



Materials for Protective Clothing : Chemically resistant materials and fabrics.

Hand Protection : Wear protective gloves.

Eye Protection : Chemical safety goggles.

Skin and Body Protection : Wear suitable protective clothing.

Respiratory Protection : In case of inadequate ventilation wear respiratory protection.

Other Information : When using, do not eat, drink or smoke.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on Basic Physical and Chemical Properties

Physical State	: Solid
Appearance	: Yellow Powder
Odor	: Odorless
Odor Threshold	: No data available
pH	: Neutral
Evaporation Rate	: No data available
Melting Point	: No data available
Freezing Point	: No data available
Boiling Point	: No data available
Flash Point	: No data available
Auto-ignition Temperature	: No data available
Decomposition Temperature	: No data available
Flammability (solid, gas)	: No data available
Vapor Pressure	: No data available
Relative Vapor Density at 20 °C	: No data available
Relative Density	: No data available
Solubility	: No data available
Partition Coefficient: N-Octanol/Water	: No data available
Viscosity	: No data available

9.2. Other Information No additional information available

SECTION 10: STABILITY AND REACTIVITY

- 10.1. Reactivity:** Hazardous reactions will not occur under normal conditions.
- 10.2. Chemical Stability:** Stable under recommended handling and storage conditions (see section 7).
- 10.3. Possibility of Hazardous Reactions:** Hazardous polymerization will not occur.
- 10.4. Conditions to Avoid:** Direct sunlight, extremely high or low temperatures, and incompatible materials. Sparks, heat, open flame and other sources of ignition.
- 10.5. Incompatible Materials:** Strong oxidizers.
- 10.6. Hazardous Decomposition Products:** Thermal decomposition generates: Carbon oxides. Nitrogen oxides. Sulfur oxides.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. 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

Skin Corrosion/Irritation: Not classified (pH: Neutral)

Serious Eye Damage/Irritation: Causes serious eye damage. (pH: Neutral)

Respiratory or Skin Sensitization: May cause an allergic skin reaction.

Germ Cell Mutagenicity: Not classified

Carcinogenicity: Not classified

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Reproductive Toxicity: Not classified

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.

Specific Target Organ Toxicity (Single Exposure): Not classified

Specific Target Organ Toxicity (Repeated Exposure): Not classified

Aspiration Hazard: Not classified

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

12.1. Toxicity

Ecology - General : Not classified.

12.2. Persistence and Degradability Not established

12.3. Bioaccumulative Potential Not established

12.4. Mobility in Soil No additional information available

12.5. Other Adverse Effects

Other Information : Avoid release to the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. 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

14.1. In Accordance with DOT Not regulated for transport

14.2. In Accordance with IMDG Not regulated for transport

14.3. In Accordance with IATA Not regulated for transport

SECTION 15: REGULATORY INFORMATION

15.1 US Federal Regulations

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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	

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

SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

Revision Date : 08/04/2015

Other Information : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200.

GHS Full Text Phrases:

Acute Tox. 3 (Oral)	Acute toxicity (oral) Category 3
Acute Tox. 4 (Oral)	Acute toxicity (oral) Category 4
Comb. Dust	Combustible Dust
Eye Dam. 1	Serious eye damage/eye irritation Category 1
Eye Irrit. 2A	Serious eye damage/eye irritation Category 2A
Skin Irrit. 2	Skin corrosion/irritation Category 2
Skin Sens. 1	Skin sensitization Category 1
STOT SE 3	Specific target organ toxicity (single exposure) Category 3
Comb. Dust	May form combustible dust concentrations in air

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H301	Toxic if swallowed
H302	Harmful if swallowed
H315	Causes skin irritation
H317	May cause an allergic skin reaction
H318	Causes serious eye damage
H319	Causes serious eye irritation
H336	May cause drowsiness or dizziness

Refer to Luitpold/American Regent prescribing information for further information at: <http://americanregent.com/AllProducts.aspx>

The information above is believed to be accurate and represents the best information currently available to American Regent. The information has not been verified and we cannot, therefore, guarantee its accuracy or completeness or adequacy for all persons and situations or as to the results to be obtained by use of the information. It is the user's obligation to evaluate and use this product safely and to comply with all applicable laws and regulations. WE MAKE NO WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR USE OR ANY OTHER WARRANTY, EXPRESSED OR IMPLIED, WITH RESPECT TO SUCH INFORMATION AND WE ASSUME NO LIABILITY RESULTING FROM ITS USE. Users should make their own investigations to determine the suitability of the information for their own particular purposes. The user assumes all risks from use of the product. In no event shall Luitpold, its subsidiaries, its affiliates and its contractors be liable for any claims, losses or damages of any third party, or for lost profits, or for any special, indirect, incidental, consequential or exemplary damages however arising, even if Luitpold has been advised of the possibility of such damages.

SDS US (GHS HazCom)