



## SAFETY DATA SHEET

### Paliperidone Extended Release Tablets

#### 1. IDENTIFICATION

**Manufacturer:**

Ascent Pharmaceuticals Inc  
400 S.Technology Dr.  
Central Islip, NY 11722

**Emergency Phone:**

1-855-221-1622

**Common Name:** Paliperidone Extended Release Tablets

**Synonym(s):** Not Applicable

**Chemical Name:** 3-{2-[4-(6-fluoro-1,2-benzoxazol-3-yl) piperidin-1-yl]ethyl}-9-hydroxy-2-methyl-4H,6H,7H,8H,9H-pyrido[1,2-a] pyrimidin-4-one

**Trade Name(s):** Paliperidone Extended Release Tablets, 1.5 mg, 3 mg, 6 mg and 9 mg.

**Therapeutic Category:** antipsychotic.

**Molecular formula:** C<sub>23</sub>H<sub>27</sub>FN<sub>4</sub>O<sub>3</sub> **Molecular Weight:** 426.4839

#### 2.HAZARDS IDENTIFICATION

Not considered hazardous when handled under normal conditions.

##### EMERGENCY OVERVIEW

**Caution Statement:** Each Paliperidone Extended Release Tablets intended for oral administration contains Paliperidone, USP and excipients generally considered to be non-toxic and non-hazardous in small quantities and under conditions of normal occupational exposure.

**Routes of Entry:** Oral

**Classification:** Not classified

**Label elements:** Not classified

**Other Hazards** No information available.

**Unknown acute toxicity:** No information available



### 3.COMPOSITION / INFORMATION ON INGREDIENTS

<u>Ingredient</u>	<u>CAS #</u>	<u>Concentration %</u>
Paliperidone, USP	144598-75-4	≈0.3-0.9%
Excipients	NA	≈99.7-99.1 %

\* All Concentrations are percent by weight.

### 4. FIRST AID MEASURES

**Inhalation:** Move in to fresh air and keep at rest. For breathing difficulties, Oxygen may be necessary. Get medical attention. If breathing stops, provide artificial respiration.

**Skin Contact:** Wash skin thoroughly with soap and water. Get medical attention if irritation persists after washing. Remove contaminated clothing and shoes. Wash contaminated clothing before reuse. Destroy or thoroughly clean contaminated shoes.

**Eye Contact:** Immediately flush with plenty of water for at least 15 minutes. If easy to do, remove contact lenses. Get medical attention.

**Ingestion:** Do not induce vomiting unless directed to do so by medical personnel. Never give liquid to an unconscious person. Get medical attention.

### 5.FIRE-FIGHTING MEASURES

**Extinguishing Media:** Water spray, CO2, dry chemical or alcohol resistant foam.

**Unusual Fire & Explosion Hazards:** Emits toxic fumes under fire conditions.

**Special Fire Fighting Procedures:** Self-Contained breathing apparatus and full protective clothing must be worn in case of fire.

**Protective Measures:** Prevent runoff from fire control or dilution from entering streams, sewers, or drinking water supply.



## 6.ACCIDENTAL RELEASE MEASURES

**Personal precautions:** Use personal protective equipment. Immediately contact emergency personnel. Keep unnecessary personnel away. Follow all firefighting procedures.

**Environmental precautions:** Do not release in to the environment.

**Spill Cleanup methods:** Use a vacuum cleaner. If not possible, moisten dust with water before it is collected with shovel, broom or the like. Collect in containers and seal securely. For waste disposal, see section 13 of the SDS.

## 7.HANDLING AND STORAGE

**Handling:** Do not breathe dust. Avoid contact with eyes, skin, and clothing. Wash thoroughly after handling.

**Storage:** Keep container tightly closed in a cool, well-ventilated place. Keep away from heat and direct sun light.

## 8.EXPOSURE CONTROLS / PERSONAL PROTECTION

Product in its final form are not considered hazardous under normal handling procedures and protective equipment is not required. The following are recommended for manufacturing or other situations where exposure to the powder may occur.

**Protective Measures:** Minimize open handling. Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas.

**Respiratory Protection:** Use a NIOSH approved respirator or an alternate approved dust mask should be used.

**Hand Protection:** Chemical resistant gloves.

**Eye Protection:** Wear safety glasses with side shields (or goggles). If the work environment or activity involves dusty conditions, mist or aerosols, wear the appropriate goggles. Wear a face shield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

**Skin and Body Protection:** Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.



**Hygiene Measures:** Wash skin thoroughly with soap and water.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

**Physical Properties:**

**Physical State:** Solid

**Form:** Tablets

## 10. STABILITY AND REACTIVITY

**Possibility of hazardous reactions:** Stable under ordinary conditions of use and storage.

**Conditions to avoid:** Excessive heat & Moisture.

**Incompatible materials:** Strong oxidizers, Strong Bases and Strong Acids.

**Hazardous Decomposition products:** Thermal decomposition or combustion may liberate irritating gases or vapors.

## 11. TOXICOLOGICAL INFORMATION

Paliperidone - Toxicity Data: Oral LD50 (rat): 65 mg/kg; Oral TDLO (woman): 5.4 mg/kg; Oral TDLO (child): 1.35 mg/kg;

## 12. ECOLOGICAL INFORMATION

**General information:** The information presented below pertains to the individual ingredients and not to the mixture(s) or final formulations.

**Ecotoxicity Effects:**

**Aquatic toxicity effects:** No data available.

**Mobility:** No data available.

**Persistence / degradability:** No data available.

**Bioaccumulation:** No data available.

**Degradation:** No data available.



### **13.DISPOSAL CONSIDERATIONS**

**Waste Disposal:** Dispose of waste must be in accordance with all applicable Federal, State and local laws.

**Measures for Avoidance and Recovery:** Incineration is the most effective method of disposal in most instances. Do not allow runoff to sewer, waterway or ground. Operations that involve the crushing or shredding of waste materials or returned goods should take into account recommended exposure limits where they exist.

### **14.TRANSPORT INFORMATION**

Packaging does not have to be labeled as Dangerous Goods/Excepted Quantity.

### **15.REGULATORY INFORMATION**

Stated regulatory information chosen primarily for possible usage of Ascent Pharmaceutical, Inc. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

Harmful when swallowed in large doses and avoid contact with eye. In case of accident, seek medical advice immediately.

### **16.OTHER INFORMATION**

**SDS Sections Revised:**

New



**GLOSSARY:**

SDS	Safety Data Sheet
NA	Not Applicable
CAS Number	Chemical Abstract Service Registry Number
NTP	National Toxicology Program
NIOSH	National Institute for Occupational Safety and Health
DOT	Department of Transportation
IMDG	International Maritime Dangerous Goods Code
ICAO	International Civil Aviation Organization
IATA	International Air Transport Association
IMO	International Maritime Organization
TSCA	Toxic Substances Control Act
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act
SARA	Superfund Amendments and Reauthorization Act
OSHA	Occupational Safety and Health Administration

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