1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

Material Name: Ziprasidine hydrochloride oral suspension

Trade Name: GEODON™, ZELDOX®
Chemical Family: Mixture
Intended Use: Pharmaceutical product used as antipsychotic

2. HAZARDS IDENTIFICATION

Appearance: White to slightly yellow uniformly dispersed opaque suspension
Signal Word: WARNING

Statement of Hazard: May cause allergic skin reaction.

Additional Hazard Information:
- **Short Term:** Ziprasidone belongs to a class of drugs which have been shown to cause electrocardiogram irregularities and arrhythmia. These effects have not been observed from occupational exposures, however, those with preexisting cardiovascular illnesses may be at increased risk from exposure.
- **Known Clinical Effects:** This drug is prescribed for antipsychotic therapy and can depress central nervous system function. Adverse effects associated with therapeutic use include sleepiness (somnolence), tiredness, nausea, constipation, dizziness, restlessness, jerky muscle movement, diarrhea, and skin rash.

EU Indication of danger: Irritant

EU Hazard Symbols: Xi

EU Risk Phrases: R43 - May cause sensitization by skin contact.


Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.
2. HAZARDS IDENTIFICATION

3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
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<td>77-92-9</td>
<td>201-069-1</td>
<td>Xi; R36</td>
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<table>
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<tr>
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</table>

Additional Information: * Proprietary Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

For the full text of the R phrases mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

5. FIRE FIGHTING MEASURES

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

Fire Fighting Procedures: During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.
Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

6. ACCIDENTAL RELEASE MEASURES

Health and Safety Precautions: Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

Measures for Environmental Protections: Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

General Handling: Minimize dust generation and accumulation. Avoid breathing dust. Avoid contact with eyes, skin and clothing. Restrict access to work area. Avoid open handling. Minimize generating airborne mists and vapors. Use process containment, local exhaust ventilation or perform work under fume hood/fume cupboard. Avoid inhalation and contact with skin, eye, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Prevent inhalation, contact with eye, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Refer to available public information for specific member state Occupational Exposure Limits.

Ziprasidone hydrochloride
Pfizer OEL TWA-8 Hr: 90µg/m³, Sensitizer

Colloidal silicon dioxide
Australia TWA 2 mg/m³
Austria OEL - MAKs Listed
Czech Republic OEL - TWA Listed
Estonia OEL - TWA Listed
Germany - TRGS 900 - TWAs 4 mg/m³
Germany (DFG) - MAK 4 mg/m³ MAK
Ireland OEL - TWAs Listed
Latvia OEL - TWA Listed
OSHA - Final PELs - Table Z-3 Mineral D: - (80)((% SiO2) mg/m³ TWA
TWA-20 mpcf
Slovenia OEL - TWA Listed

Sodium chloride
8. EXPOSURE CONTROLS / PERSONAL PROTECTION


Engineering Controls: Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

Environmental Exposure Controls: Refer to specific Member State legislation for requirements under Community environmental legislation.

Personal Protective Equipment: Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

- Hands: Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.
- Eyes: Wear safety glasses or goggles if eye contact is possible.
- Skin: Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.
- Respiratory protection: If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

9. PHYSICAL AND CHEMICAL PROPERTIES

- Physical State: Suspension
- Color: White to slightly yellow
- Odor: Cherry
- Molecular Weight: Mixture
- pH: 3.5 - 4.5
- Polymerization: Will not occur

10. STABILITY AND REACTIVITY

- Stability: Stable under normal conditions of use.
- Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.
- Incompatible Materials: As a precautionary measure, keep away from strong oxidizers

11. TOXICOLOGICAL INFORMATION

- General Information: The information included in this section describes the potential hazards of ziprasidone in free base, hydrochloride and/or mesylate forms. The remaining information describes the potential hazards of the individual ingredients.

Acute Toxicity: (Species, Route, End Point, Dose)

- Methylparaben
  - Mouse Oral LD50 > 8000 mg/kg
  - Rat Oral LD50 2280 mg/kg

- Citric acid
  - Rat Oral LD50 3000 mg/kg
11. TOXICOLOGICAL INFORMATION

Sodium chloride
Rat Oral LD50 3000 mg/kg
Mouse Oral LD50 4000 mg/kg

Polysorbate 80
Rat Oral LD50 25 g/kg

Xanthan gum
Rat Oral LD50 > 5000 mg/kg

Ziprasidone hydrochloride
Rat Oral LD50 > 2000 mg/kg
Rat IP LD50 > 2000 mg/kg
Mouse Oral LD50 > 2000 mg/kg
Mouse IP LD50 500-1000 mg/kg
Rabbit Dermal LD50 > 2000 mg/kg

Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Irritation / Sensitization: (Study Type, Species, Severity)

Citric acid
Eye Irritation Rabbit Severe
Skin Irritation Rabbit Mild

Sodium chloride
Eye Irritation Rabbit Moderate
Skin Irritation Rabbit Mild

Ziprasidone hydrochloride
Eye Irritation Rabbit Non-irritating
Skin Irritation Rabbit Non-irritating
Skin Sensitization - GPMT Guinea Pig Positive

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Ziprasidone hydrochloride
6 Month(s) Rat Oral 40 mg/kg/day LOAEL Central nervous system, Liver
6 Month(s) Dog Oral 40 mg/kg/day LOAEL Central Nervous System Liver
1 Month(s) Rat Oral 160 mg/kg/day NOAEL Central Nervous System
12 Month(s) Dog Oral 10 mg/kg/day NOAEL Central Nervous System

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Ziprasidone hydrochloride
Reproductive & Fertility Rat Oral 40 mg/kg/day NOAEL Negative
Peri-/Postnatal Development Rat 5 mg/kg/day NOAEL Embryotoxicity, Fetotoxicity
Embryo / Fetal Development Rat Oral 10 mg/kg/day NOAEL Not Teratogenic
Embryo / Fetal Development Rabbit Oral 30 mg/kg/day NOAEL Not Teratogenic
Liver Central nervous system

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)
11. TOXICOLOGICAL INFORMATION

Ziprasidone hydrochloride

*In Vitro* Human Lymphocytes Negative
*In Vivo* Mouse Bone Marrow Negative
*In Vitro* Bacterial Mutagenicity (Ames) *Salmonella* Negative
*In Vitro* Mammalian Cell Mutagenicity Mouse Lymphoma Negative

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Ziprasidone hydrochloride
2 Year(s) Rat Oral 12 mg/kg/day Not carcinogenic
2 Year(s) Mouse Oral 200 mg/kg/day Not carcinogenic

Carcinogen Status: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

Colloidal silicon dioxide
IARC: Group 3

12. ECOLOGICAL INFORMATION

Environmental Overview: This substance was not acutely toxic to aquatic organisms at its maximum solubility. See aquatic toxicity data below.

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

Ziprasidone hydrochloride

*Daphnia magna* (Water Flea) OECD EC50 48 Hours > 0.04 mg/L
*Pseudokirchneriella subcapitata* (Green Alga) TAD EC50 72 Hours 0.01 mg/L
*Selenastrum capricornutum* (Green Alga) OECD EC50 72 Hours > 0.76 mg/L
*Pimephales promelas* (Fathead Minnow) TAD EC50 96 Hours > 0.035 mg/L
*Pimephales promelas* (Fathead Minnow) OECD NOEC 32 Days 0.027 mg/L

Aquatic Toxicity Comments: A greater than (>) symbol indicates that acute ecotoxicity was not observed at the maximum solubility. Since the substance is insoluble in aqueous solutions above this concentration, an acute ecotoxicity value (i.e. LC/EC50) is not achievable.

Ziprasidone hydrochloride
Activated sludge OECD EC50 3 Hours > 1000 mg/L

13. DISPOSAL CONSIDERATIONS

Disposal Procedures: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

14. TRANSPORT INFORMATION

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.
## 15. REGULATORY INFORMATION

**EU Symbol:**  
Xi

**EU Indication of danger:**  
Irritant

**EU Risk Phrases:**  
R43 - May cause sensitization by skin contact.

**EU Safety Phrases:**  
S24 - Avoid contact with skin.  
S37 - Wear suitable gloves.

**OSHA Label:**  
WARNING  
May cause allergic skin reaction.

### Canada - WHMIS: Classifications

**WHMIS hazard class:**  
Class D, Division 2, Subdivision B

### Xylitol

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<tr>
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### Methylparaben

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### Propylparaben

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### Sodium citrate, dihydrate

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### Xanthan gum

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15. REGULATORY INFORMATION

Polysorbate 80

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Colloidal silicon dioxide

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Water, purified

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Sodium chloride

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Citric acid

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16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R43 - May cause sensitization by skin contact.
R48/22 - Harmful: danger of serious damage to health by prolonged exposure if swallowed.

Data Sources: Pfizer proprietary drug development information. Safety data sheets for individual ingredients.

Reasons for Revision: Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 4 - First Aid Measures. Updated Section 5 - Fire Fighting Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 10 - Stability and Reactivity. Updated Section 11 - Toxicology Information. Updated Section 15 - Regulatory Information.

Prepared by: Toxicology and Hazard Communication
Pfizer Global Environment, Health, and Safety Operations

Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet