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

Material Name: Ziprasidone hydrochloride capsules

Trade Name: GEODON™
Chemical Family: Benzisothiazol derivative
Intended Use: Pharmaceutical product used as antipsychotic

2. HAZARDS IDENTIFICATION

Appearance: Capsules: 20 mg (blue/white), 40 mg (blue/blue), 60 mg (white/white), and 80 mg (blue/white)
Signal Word: WARNING

Statement of Hazard: May cause allergic skin reaction.
May cause damage to liver through prolonged or repeated exposure.

Additional Hazard Information:
Short Term: Antipsychotic drug: causes central nervous system effects
Known Clinical Effects: 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: Xn

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


Additional Information: For a more detailed discussion of potential health hazards and toxicity see Section 11.
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>
<th>Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ziprasidone hydrochloride</td>
<td>138982-67-9</td>
<td>Not listed</td>
<td>Xn;R43-48/22</td>
<td>22-30</td>
</tr>
<tr>
<td>Starch, pregelatinized</td>
<td>9005-25-8</td>
<td>232-679-6</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>209-150-3</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lactose NF, monohydrate</td>
<td>64044-51-5</td>
<td>Not listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Hard gelatin capsules</td>
<td>MIXTURE</td>
<td>Not listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</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.

Additional Information: This material is not expected to support combustion

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 spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. 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. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, 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

Starch, pregelatinized
- ACGIH Threshold Limit Value (TWA): 10 mg/m³ TWA
- Australia TWA: 10 mg/m³
- Belgium OEL - TWA: Listed
- Bulgaria OEL - TWA: Listed
- Czech Republic OEL - TWA: Listed
- Greece OEL - TWA: Listed
- Ireland OEL - TWAs: Listed
- OSHA - Final PELS - TWAs: 15 mg/m³ total, 5 mg/m³
- Portugal OEL - TWA: Listed
- Spain OEL - TWA: Listed

Magnesium stearate
- ACGIH Threshold Limit Value (TWA): 10 mg/m³ TWA
- Australia TWA: 10 mg/m³
- Belgium OEL - TWA: Listed
- Ireland OEL - TWAs: Listed
- Lithuania OEL - TWA: Listed
- Portugal OEL - TWA: Listed
- Spain OEL - TWA: Listed
- Sweden OEL - TWAs: Listed

The exposure limit(s) listed for solid components are only relevant if dust may be generated.

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: Capsule
Color:

- 20 mg (blue/white), 40 mg (blue/blue), 60 mg (white/white), and 80 mg (blue/white)

Molecular Formula: Mixture
Molecular Weight: Mixture

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 the individual ingredients.

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

**Magnesium stearate**
- Rat Oral LD50 > 2000 mg/kg
- Rat Inhalation LC50 > 2000 mg/m³

**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
11. TOXICOLOGICAL INFORMATION

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)

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

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

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.

12. ECOLOGICAL INFORMATION

Environmental Overview: The active ingredient in this mixture 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
12. ECOLOGICAL INFORMATION

<table>
<thead>
<tr>
<th>Species</th>
<th>Method</th>
<th>End Point</th>
<th>Duration</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Pimephales promelas</em> (Fathead Minnow)</td>
<td>TAD</td>
<td>EC50</td>
<td>96 Hours</td>
<td>&gt; 0.035 mg/L</td>
</tr>
<tr>
<td><em>Pimephales promelas</em> (Fathead Minnow)</td>
<td>OECD</td>
<td>NOEC</td>
<td>32 Days</td>
<td>0.027 mg/L</td>
</tr>
</tbody>
</table>

Bacterial Inhibition: (Species, Method, End Point, Duration, Result)

**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: Xn
EU Indication of danger: Irritant
EU Risk Phrases:
R43 - May cause sensitization by skin contact.
R48/22 - Harmful: danger of serious damage to health by prolonged exposure if swallowed.
EU Safety Phrases:
S22 - Do not breathe dust.
S24 - Avoid contact with skin.
S53 - Avoid exposure - obtain special instructions before use.

OSHA Label:
WARNING
May cause allergic skin reaction.
May cause damage to liver through prolonged or repeated exposure.

Canada - WHMIS: Classifications

WHMIS hazard class:
Class D, Division 2, Subdivision B
15. REGULATORY INFORMATION

Starch, pregelatinized
   Inventory - United States TSCA - Sect. 8(b)   Listed
   Australia (AICS):                           Listed
   REACH - Annex IV - Exemptions from the obligations of Register:
   EU EINECS/ELINCS List                      232-679-6

Lactose NF, monohydrate
   Australia (AICS):                           Listed

Magnesium stearate
   Inventory - United States TSCA - Sect. 8(b)   Listed
   Australia (AICS):                           Listed
   EU EINECS/ELINCS List                      209-150-3

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 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 4 - First Aid Measures. Updated Section 5 - Fire Fighting Measures. Updated Section 6 - Accidental Release 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 13 - Disposal Considerations. Updated Section 15 - Regulatory Information.

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

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End of Safety Data Sheet