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

Product Identifier

Material Name: Ziprasidone hydrochloride capsules

Trade Name: GEODON; ZELDOX; EMPREVAL

Chemical Family: Benzisothiazol derivative

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Pharmaceutical product used as antipsychotic

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification

Skin Sensitization: Category 1
Specific target organ systemic toxicity (repeated exposure): Category 2

EU Classification:

EU Indication of danger: Irritant
Harmful

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

Label Elements

Signal Word: Warning

Hazard Statements:
H317 - May cause an allergic skin reaction
H373 - May cause damage to organs through prolonged or repeated exposure
Precautionary Statements:

- P260 - Do not breathe dust/fume/gas/mist/vapors/spray
- P272 - Contaminated work clothing should not be allowed out of the workplace
- P280 - Wear protective gloves/protective clothing/eye protection/face protection
- P302+ P352 - IF ON SKIN: Wash with plenty of soap and water
- P314 - Get medical attention/advice if you feel unwell
- P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention
- P321 - Specific treatment (see supplemental first aid instructions on this label)
- P363 - Wash contaminated clothing before reuse
- P501 - Dispose of contents/container in accordance with all local and national regulations

Other Hazards

Australian Hazard Classification (NOHSC):


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.

Additional Information:

For a more detailed discussion of potential health hazards and toxicity see Section 11.

3. COMPOSITION / INFORMATION ON INGREDIENTS

**Hazardous**

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>209-150-3</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Starch, pregelatinized</td>
<td>9005-25-8</td>
<td>232-679-6</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Ziprasidone hydrochloride</td>
<td>138982-67-9</td>
<td>Not Listed</td>
<td>Xi;R43</td>
<td>Skin Sens.1 (H317)</td>
<td>22-30</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>STOT RE.2 (H373)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

For the full text of the R phrases and CLP/GHS abbreviations mentioned in this Section, see Section 16
4. FIRST AID MEASURES

Description of 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.

Most Important Symptoms and Effects, Both Acute and Delayed

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.

Medical Conditions Aggravated by Exposure:  None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician:  None

5. FIRE FIGHTING MEASURES

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

Special Hazards Arising from the Substance or Mixture

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

Fire / Explosion Hazards:  Fine particles (such as dust and mists) may fuel fires/explosions.

Advice for Fire-Fighters

During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

Additional Information:  This material is not expected to support combustion

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

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

Environmental Precautions

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

Methods and Material for Containment and Cleaning Up

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.

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

Precautions for Safe Handling
7. HANDLING AND STORAGE

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.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging.
Specific end use(s): Pharmaceutical drug product

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Magnesium stearate
ACGIH Threshold Limit Value (TWA) 10 mg/m³
Lithuania OEL - TWA 5 mg/m³
Sweden OEL - TWAs 5 mg/m³

Starch, pregelatinized
ACGIH Threshold Limit Value (TWA) 10 mg/m³
Australia TWA 10 mg/m³
Belgium OEL - TWA 10 mg/m³
Bulgaria OEL - TWA 10.0 mg/m³
Czech Republic OEL - TWA 4.0 mg/m³
Greece OEL - TWA 10 mg/m³
              5 mg/m³
Ireland OEL - TWAs 10 mg/m³
              4 mg/m³
OSHA - Final PELS - TWAs: 15 mg/m³
Portugal OEL - TWA 10 mg/m³
Slovakia OEL - TWA 4 mg/m³
Spain OEL - TWA 10 mg/m³
Switzerland OEL -TWAs 3 mg/m³

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

Exposure Controls
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.

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)

**Odor:** No data available

**Molecular Formula:** Mixture

**Odor Threshold:** No data available

**Molecular Weight:** Mixture

Solvent Solubility: No data available

Water Solubility: No data available

pH: No data available

Melting/Freezing Point (°C): No data available

Boiling Point (°C): No data available

Partition Coefficient: (Method, pH, Endpoint, Value)

Ziprasidone hydrochloride

Measured Log P 3.44

Hard gelatin capsules

No data available

Starch, pregelatinized

No data available

Lactose NF, monohydrate

No data available

Magnesium stearate

No data available

**Decomposition Temperature (°C):** No data available.

Evaporation Rate (Gram/s): No data available

Vapor Pressure (kPa): No data available

Vapor Density (g/ml): No data available

Relative Density: No data available

Viscosity: No data available

Flammability:

Autoignition Temperature (Solid) (°C): No data available

Flammability (Solids): No data available

Flash Point (Liquid) (°C): No data available

Upper Explosive Limits (Liquid) (% by Vol.): No data available

Lower Explosive Limits (Liquid) (% by Vol.): No data available

Polymerization: Will not occur

10. STABILITY AND REACTIVITY

**Reactivity:** No data available

**Chemical Stability:** Stable under normal conditions of use.

**Possibility of Hazardous Reactions**

**Oxidizing Properties:** No data available

**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

**Hazardous Decomposition Products:** No data available
11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects
General Information: The information included in this section describes the potential hazards of the individual ingredients.

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.

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

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

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

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
11. TOXICOLOGICAL INFORMATION

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.

Toxicity:

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

<table>
<thead>
<tr>
<th>Species</th>
<th>Method</th>
<th>End Point</th>
<th>Duration</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Daphnia magna (Water Flea)</td>
<td>OECD</td>
<td>EC50</td>
<td>48 Hours</td>
<td>&gt; 0.048 mg/L</td>
</tr>
<tr>
<td>Pimephales promelas (Fathead Minnow)</td>
<td>TAD</td>
<td>LC50</td>
<td>96 Hours</td>
<td>&gt; 0.035 mg/L</td>
</tr>
<tr>
<td>Selenastrum capricornutum (Green Alga)</td>
<td>OECD</td>
<td>ErC50</td>
<td>72 Hours</td>
<td>&gt; 0.12 mg/L</td>
</tr>
<tr>
<td>Daphnia magna (Water Flea)</td>
<td>OECD</td>
<td>NOEC</td>
<td>21 Days</td>
<td>0.005 mg/L</td>
</tr>
<tr>
<td>Ceriodaphnia dubia (Daphnids)</td>
<td>OECD</td>
<td>NOEC</td>
<td>7 Days</td>
<td>0.021 mg/L</td>
</tr>
</tbody>
</table>

Bacterial Inhibition: (Inoculum, Method, End Point, Result)

Ziprasidone hydrochloride
Activated sludge  OECD  EC50  > 1000 mg/L

Persistence and Degradability:
Biodegradation: (Method, Inoculum, Biodeg Study, Result, Endpoint, Duration, Classification)
Ziprasidone hydrochloride  Ready  36% After  28 Day(s)  Not Ready

Bio-accumulative Potential:
Partition Coefficient: (Method, pH, Endpoint, Value)
Ziprasidone hydrochloride
Measured  Log P  3.44

Mobility in Soil: No data available

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods: 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.
SAFETY DATA SHEET

Material Name: Ziprasidone hydrochloride capsules
Revision date: 11-Jul-2014

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Canada - WHMIS: Classifications
WHMIS hazard class:
Class D, Division 2, Subdivision B

Hard gelatin capsules
CERCLA/SARA 313 Emission reporting Not Listed
California Proposition 65 Not Listed
EU EINECS/ELINCS List Not Listed

Lactose NF, monohydrate
CERCLA/SARA 313 Emission reporting Not Listed
California Proposition 65 Not Listed
Australia (AICS): Present
REACH - Annex IV - Exemptions from the obligations of Register:
EU EINECS/ELINCS List Not Listed

Magnesium stearate
CERCLA/SARA 313 Emission reporting Not Listed
California Proposition 65 Not Listed
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS/ELINCS List 209-150-3

Starch, pregelatinized
CERCLA/SARA 313 Emission reporting Not Listed
California Proposition 65 Not Listed
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
REACH - Annex IV - Exemptions from the obligations of Register: Present
15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>EU EINECS/ELINCS List</th>
<th>232-679-6</th>
</tr>
</thead>
</table>

Ziprasidone hydrochloride
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- EU EINECS/ELINCS List: Not Listed

16. OTHER INFORMATION

Text of R phrases and GHS Classification abbreviations mentioned in Section 3

- Sensitization, skin-Cat.1; H317 - May cause an allergic skin reaction
- Specific target organ toxicity, repeated exposure-Cat.2; H373 - May cause damage to organs through prolonged or repeated exposure

Xn - Harmful
Xi - Irritant

- 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 7 - Handling and Storage
- Updated Section 8 - Exposure Controls / Personal Protection
- Updated Section 11 - Toxicology Information
- Updated Section 15 - Regulatory Information
- Updated Section 16 - Other Information
- Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking.

Revision date: 11-Jul-2014
Prepared by: Product Stewardship 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