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

Product Identifier
Material Name: Ziprasidone mesylate for injection
Trade Name: GEODON IM; ZELDOX IM
Chemical Family: Mixture

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against
Intended Use: Pharmaceutical product used as antipsychotic

Details of the Supplier of the Safety Data Sheet
Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-800-879-3477

Pfizer Ltd
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CT13 9NJ
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Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
International CHEMTREC (24 hours): +1-703-527-3887

Contact E-Mail: pfizer-MSDS@pfizer.com

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture
GHS - Classification
Skin Sensitization: Category 1

US OSHA Specific - Classification
Physical Hazard: Combustible Dust

EU Classification:
EU Indication of danger: Irritant

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

Label Elements
Signal Word: Warning
Hazard Statements:
H317 - May cause an allergic skin reaction
May form combustible dust concentrations in air

Precautionary Statements:
P261 - Avoid breathing 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
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
SAFETY DATA SHEET

Material Name: Ziprasidone mesylate for injection
Revision date: 28-Feb-2015

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>Sulfobutylether b-cyclodextrin sodium (SBECD)</td>
<td>7585-39-9</td>
<td>231-493-2</td>
<td>Xi;43</td>
<td>Skin Sens. 1 (H317)</td>
<td>*</td>
</tr>
<tr>
<td>Ziprasidone mesylate trihydrate</td>
<td>185021-64-1</td>
<td>Not Listed</td>
<td>Xn;R48/22</td>
<td>STOT RE.2 (H373)</td>
<td>8.5</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**

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
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.

6. ACCIDENTAL RELEASE MEASURES

Personnel 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
Minimize dust generation and accumulation. Avoid breathing dust. 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
- **Sulfobutylylether b-cyclodextrin sodium (SBECD)**
  - Pfizer OEL TWA-8 Hr: 3000µg/m³
- **Ziprasidone mesylate trihydrate**
  - Pfizer OEL TWA-8 Hr: 90µg/m³, (as free base)

Exposure Controls
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.

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: Lyophilized powder
Odor: No data available.
Molecular Formula: Mixture
Solvent Solubility: No data available
Water Solubility: No data available
Solubility: Soluble: Water
pH: 3.5 - 4.6
Melting/Freezing Point (°C): No data available
Boiling Point (°C): No data available.
Partition Coefficient: (Method, pH, Endpoint, Value)
Sulfobutylether b-cyclodextrin sodium (SBECD)
No data available
Ziprasidone mesylate trihydrate
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.
10. STABILITY AND REACTIVITY

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: Drugs of this class have been associated with rare, but potentially serious cardiac events. These events 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. Common adverse effects include sleepiness (somnolence), tiredness, dizziness, restlessness, nausea, constipation, jerky muscle movement, diarrhea, and skin rash. Sulfobutylether b-cyclodextrin sodium (SBEDC) has been associated with toxic effects in the kidney.

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

Sulfobutylether b-cyclodextrin sodium (SBEDC)
Rat Oral LD50 > 2000 mg/kg
Rat/Mouse IV LD50 > 2000mg/kg

Ziprasidone mesylate trihydrate
Rat Dermal LD50 > 2000 mg/kg
Rat Oral LD50 > 2000mg/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.

Acute Toxicity Comments C
Ziprasidone hydrochloride tested negative for phototoxicity in mice and for anaphylaxis/antigenicity in guinea pigs.

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

Sulfobutylether b-cyclodextrin sodium (SBEDC)
Eye Irritation Rabbit Non-irritating
Skin Irritation Rabbit Non-irritating
Skin Sensitization - GPMT Guinea Pig Positive

Ziprasidone mesylate trihydrate
Skin Irritation Rabbit Non-irritating
Eye Irritation Rabbit Non-irritating

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

Sulfobutylether b-cyclodextrin sodium (SBEDC)
6 Month(s) Rat Intravenous 600 mg/kg/day NOAEL Kidney, Liver
1 Month(s) Rat Intravenous 160 mg/kg/day NOAEL Kidney
6 Month(s) Dog Intravenous 600 mg/kg/day NOAEL Kidney
1 Month(s) Dog Intravenous 120 mg/kg/day NOAEL Kidney

Ziprasidone mesylate trihydrate
6 Month(s) Rat Oral 40 mg/kg/day LOAEL Central nervous system, Liver
11. TOXICOLOGICAL INFORMATION

Chronic Toxicity:
Ziprasidone hydrochloride was evaluated orally in dogs at doses up to 20 mg/kg/day for 12 months with only slight body weight effects in the high dose males.

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

Ziprasidone mesylate trihydrate
Reproductive & Fertility Rat Oral 40 mg/kg/day NOAEL Negative
Peri-/Postnatal Development Rat Oral 10 mg/kg/day NOAEL Not Teratogenic

Sulfobutylether b-cyclodextrin sodium (SBEDC)
Fertility and Embryonic Development Rat Intravenous 1500 mg/kg/day NOAEL No effects at maximum dose
Embryo / Fetal Development Rabbit Intravenous 1500 mg/kg/day NOAEL Not Teratogenic
Prenatal & Postnatal Development Rat Intravenous 600 mg/kg/day NOAEL Maternal Toxicity

Ziprasidone mesylate trihydrate
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)

Sulfobutylether b-cyclodextrin sodium (SBEDC)
Bacterial Mutagenicity (Ames) Salmonella, E. coli Negative
In Vitro Chromosome Aberration Human Lymphocytes Negative
Mammalian Cell Mutagenicity Chinese Hamster Ovary (CHO) cells HGPRT Negative
In Vivo Micronucleus Mouse Bone Marrow Negative

Ziprasidone mesylate trihydrate
In Vitro Human Lymphocytes Negative
In Vivo Mouse Bone Marrow Negative

Bacterial Mutagenicity (Ames) Salmonella Negative

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

Ziprasidone mesylate trihydrate
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 environmental characteristics of this mixture have not been fully evaluated. No harmful effects to aquatic organisms are expected based on the effects of the individual ingredients.

Toxicity:

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

Sulfobutylether b-cyclodextrin sodium (SBEDC)
SAFETY DATA SHEET

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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.

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

Sulfobutylether b-cyclodextrin sodium (SBECD)
CERCLA/SARA 313 Emission reporting Not Listed
California Proposition 65 Not Listed

Oncorhynchus mykiss (Rainbow Trout) OECD LC50 96 Hours > 220 mg/L
Daphnia magna (Water Flea) OECD EC-50 48 Hours > 96 mg/L
Green algae OECD IC50 72 Hours > 100 mg/L
Aquatic Toxicity Comments: A greater than symbol (>) indicates that aquatic toxicity was not observed at the maximum dose tested.

Persistence and Degradability: No data available
Bio-accumulative Potential: No data available
Mobility in Soil: No data available

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15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>Inventory - United States TSCA - Sect. 8(b)</th>
<th>Present</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia (AICS):</td>
<td>Present</td>
</tr>
<tr>
<td>EU EINECS/ELINCS List</td>
<td>231-493-2</td>
</tr>
</tbody>
</table>

Ziprasidone mesylate trihydrate

<table>
<thead>
<tr>
<th>CERCLA/SARA 313 Emission reporting</th>
<th>Not Listed</th>
</tr>
</thead>
<tbody>
<tr>
<td>California Proposition 65</td>
<td>Not Listed</td>
</tr>
<tr>
<td>EU EINECS/ELINCS List</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

16. OTHER INFORMATION

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

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

Xi - Irritant
Xn - Harmful

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. Publicly available toxicity information.

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 7 - Handling and Storage. Updated Section 11 - Toxicology Information. Updated Section 16 - Other Information.

Revision date: 28-Feb-2015

Prepared by: Product Stewardship Hazard Communication

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