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

Product Identifier
Material Name: Sonata (Zaleplon) Capsules
Trade Name: SONATA
Chemical Family: Nonbenzodiazepine pyrazolopyrimidine

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

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
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161

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
Reproductive Toxicity: Category 2
Effects on or via lactation

EU Classification:
EU Indication of danger: Toxic to Reproduction: Category 3

EU Risk Phrases:
R62 - Possible risk of impaired fertility.
R63 - Possible risk of harm to the unborn child.
R64 - May cause harm to breastfed babies.

Label Elements
Signal Word: Warning
Hazard Statements:
H361fd - Suspected of damaging fertility. Suspected of damaging the unborn child.
H362 - May cause harm to breast-fed children
Precautionary Statements:

P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P281 - Use personal protective equipment as required
P263 - Avoid contact during pregnancy/while nursing
P264 - Wash hands thoroughly after handling
P270 - Do not eat, drink or smoke when using this product
P308 + P313 - IF exposed or concerned: Get medical attention/advice
P405 - Store locked up
P501 - Dispose of contents/container in accordance with all local and national regulations

Other Hazards

No data available

Australian Hazard Classification (NOHSC):


Note:

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

3. COMPOSITION / INFORMATION ON INGREDIENTS

<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>
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</thead>
<tbody>
<tr>
<td>Microcrystalline cellulose</td>
<td>9004-34-6</td>
<td>232-674-9</td>
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<td>Not Listed</td>
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<tr>
<td>Starch, pregelatinized</td>
<td>9005-25-8</td>
<td>232-679-6</td>
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<tr>
<td>Colloidal silicon dioxide</td>
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<td>Repr. Cat.3; R62-63-64</td>
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<td>5 or 10mg***</td>
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<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
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<tbody>
<tr>
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<td>Stearic acid</td>
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<td>205-788-1</td>
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<td>Not Listed</td>
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</table>

Additional Information:

* Proprietary
*** per tablet/capsule/lozenge/suppository

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:**
Extinguish fires with CO2, extinguishing powder, foam, or water.

**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

**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
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.

Microcrystalline cellulose
ACGIH Threshold Limit Value (TWA) 10 mg/m³
Australia TWA 10 mg/m³
Belgium OEL - TWA 10 mg/m³
Estonia OEL - TWA 10 mg/m³
France OEL - TWA 10 mg/m³
Ireland OEL - TWA 10 mg/m³
Latvia OEL - TWA 2 mg/m³
OSHA - Final PELS - TWAs: 15 mg/m³
Portugal OEL - TWA 10 mg/m³
Romania OEL - TWA 10 mg/m³
Russia OEL - TWA 6 mg/m³
Spain OEL - TWA 10 mg/m³
Switzerland OEL - TWAs 3 mg/m³
Vietnam OEL - TWAs 10 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
Ireland OEL - TWAs 5 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

Colloidal silicon dioxide
### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Location</th>
<th>Exposure Limit</th>
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</thead>
<tbody>
<tr>
<td>Australia TWA</td>
<td>2 mg/m³</td>
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<tr>
<td>Austria OEL - MAKs</td>
<td>4 mg/m³</td>
</tr>
<tr>
<td>Czech Republic OEL - TWA</td>
<td>0.1 mg/m³</td>
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<tr>
<td>Estonia OEL - TWA</td>
<td>2 mg/m³</td>
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<tr>
<td>Finland OEL - TWA</td>
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<tr>
<td>Germany - TRGS 900 - TWAs</td>
<td>4 mg/m³</td>
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<tr>
<td>Germany (DFG) - MAK</td>
<td>4 mg/m³</td>
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<tr>
<td>Ireland OEL - TWAs</td>
<td>6 mg/m³</td>
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<tr>
<td>Latvia OEL - TWA</td>
<td>1 mg/m³</td>
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<tr>
<td>OSHA - Final PELs - Table Z-3 Mineral D:</td>
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</tr>
<tr>
<td>Slovakia OEL - TWA</td>
<td>4.0 mg/m³</td>
</tr>
<tr>
<td>Switzerland OEL - TWAs</td>
<td>4 mg/m³</td>
</tr>
<tr>
<td></td>
<td>0.3 mg/m³</td>
</tr>
</tbody>
</table>

**Sodium lauryl sulfate**
- Pfizer OEL TWA-8 Hr: 0.3 mg/m³

**Zaleplon**
- Pfizer OEL TWA-8 Hr: 30µg/m³

**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

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
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</thead>
<tbody>
<tr>
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<tr>
<td>Odor</td>
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<td>Molecular Formula</td>
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<td>Color</td>
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<td>Odor Threshold</td>
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<tr>
<td>Molecular Weight</td>
<td>Mixture</td>
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<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
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<tbody>
<tr>
<td>Solvent Solubility</td>
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<tr>
<td>Water Solubility</td>
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<tr>
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<td>Melting/Freezing Point (°C):</td>
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<tr>
<td>Boiling Point (°C):</td>
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<tr>
<td>Partition Coefficient: (Method, pH, Endpoint, Value)</td>
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<tr>
<td>Microcrystalline cellulose</td>
<td>No data available</td>
</tr>
</tbody>
</table>
9. PHYSICAL AND CHEMICAL PROPERTIES

Lactose Monohydrate
No data available
Sodium lauryl sulfate
No data available
Colloidal silicon dioxide
No data available
Stearic acid
No data available
Hard gelatin capsules
No data available
Zaleplon
No data available
Starch, pregelatinized
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

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.
Long Term: Repeat-dose studies in animals have shown a potential to cause adverse effects on fertility and developing fetus.
Known Clinical Effects: Adverse effects associated with therapeutic use include abdominal pain, amnesia, dizziness, drowsiness, headache, nausea, sleepiness (somnolence), tingling sensation, allergic reaction, weakness, and may be secreted in human breast milk.

Acute Toxicity: (Species, Route, End Point, Dose)
11. TOXICOLOGICAL INFORMATION

Microcrystalline cellulose
Rat Oral LD50 > 5000 mg/kg
Rabbit Dermal LD50 > 2000 mg/kg

Lactose Monohydrate
Rat Oral LD50 29700 mg/kg

Sodium lauryl sulfate
Rat Oral LD50 1288 mg/kg

Stearic acid
Rat Oral LD50 > 4640 mg/kg
Rabbit Dermal LD50 > 5000 mg/kg

Zaleplon
Rat Oral Minimum Lethal Dose > 1000 mg/kg
Dog Oral Minimum Lethal Dose > 1000mg/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)

Microcrystalline cellulose
Skin Irritation Rabbit Non-irritating
Eye Irritation Rabbit Non-irritating

Sodium lauryl sulfate
Eye Irritation Rabbit Moderate
Skin Irritation Rabbit Mild Moderate
Skin Sensitization - GPMT Guinea Pig Negative
Skin Sensitization - LLNA Mouse Negative

Stearic acid
Skin Irritation Rabbit Moderate
Eye Irritation Rabbit Mild

Zaleplon
Eye Irritation Rabbit Non-irritating
Skin Irritation Rabbit Non-irritating

Stearic acid
30 Week(s) Rat Oral 300 ppm LOAEL Adipose tissue

Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Zaleplon
Reproductive & Fertility Rat Oral 100 mg/kg/day LOAEL Maternal toxicity, Fertility
Embryo / Fetal Development Rat Oral 10 mg/kg/day NOAEL Not Teratogenic, Developmental toxicity, Maternal Toxicity
Embryo / Fetal Development Rabbit No route specified 50 mg/kg/day NOAEL Not Teratogenic
Prenatal & Postnatal Development Rat No route specified 1 mg/kg/day NOEL Developmental toxicity
11. TOXICOLOGICAL INFORMATION

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

**Lactose Monohydrate**  
*In Vitro* Bacterial Mutagenicity (Ames)  Negative

**Sodium lauryl sulfate**  
Bacterial Mutagenicity (Ames)  *Salmonella*  Negative

**Stearic acid**  
*In Vitro* Bacterial Mutagenicity (Ames)  *Salmonella*  Negative  
Unscheduled DNA Synthesis  *E. coli*  Negative

**Zaleplon**  
*In Vitro* Chromosome Aberration  Human Lymphocytes  Negative  
*In Vitro* Bacterial Mutagenicity (Ames)  *Salmonella*  Negative  
*In Vivo* Chromosome Aberration  Mouse Bone Marrow  Negative  
*In Vitro* Chromosome Aberration  Chinese Hamster Ovary (CHO) cells  Positive  
*In Vivo* Micronucleus  Mouse Bone Marrow  Negative

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

**Stearic acid**  
26 Week(s)  Rat  Subcutaneous  0.5 mg/kg/week  NOAEL  Not carcinogenic  
52 Week(s)  Mouse  Subcutaneous  0.05 mg/kg/week  LOAEL  Tumors

**Zaleplon**  
2 Year(s)  Rat  Oral, in feed  20 mg/kg/day  NOAEL  Not carcinogenic  
2 Year(s)  Mouse  Oral, in feed  200 mg/kg/day  LOAEL  Liver

**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 (Not Classifiable)

12. ECOLOGICAL INFORMATION

**Environmental Overview:**  
Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided.

**Toxicity:**

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

**Sodium lauryl sulfate**  
*Oncorhynchus mykiss* (Rainbow Trout)  LC50  96 Hours  3.6 mg/L

**Persistence and Degradability:**  
No data available

**Bio-accumulative Potential:**  
No data available

**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.

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 A

Microcrystalline cellulose
CERCLA/SARA 313 Emission reporting Not Listed
California Proposition 65 carcinogen initial date 12/18/09
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
REACH - Annex XVII - Restrictions on Certain Dangerous Substances: Use restricted. See item 9[f], powder
EU EINECS/ELINCS List 232-674-9

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
### 15. REGULATORY INFORMATION

**Hard gelatin capsules**

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<tbody>
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<td>California Proposition 65</td>
<td>Not Listed</td>
</tr>
<tr>
<td>EU EINECS/ELINCS List</td>
<td>Not Listed</td>
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**Lactose Monohydrate**

<table>
<thead>
<tr>
<th>Category</th>
<th>Status</th>
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<tbody>
<tr>
<td>CERCLA/SARA 313 Emission reporting</td>
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<td>California Proposition 65</td>
<td>Not Listed</td>
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<td>Australia (AICS):</td>
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<tr>
<td>REACH - Annex IV - Exemptions from the obligations of Register:</td>
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<tr>
<td>EU EINECS/ELINCS List</td>
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**Colloidal silicon dioxide**

<table>
<thead>
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<th>Category</th>
<th>Status</th>
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</thead>
<tbody>
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<td>CERCLA/SARA 313 Emission reporting</td>
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**Stearic acid**

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**Sodium lauryl sulfate**

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<th>Status</th>
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<tbody>
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<td>California Proposition 65</td>
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<td>Australia (AICS):</td>
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<td>Standard for the Uniform Scheduling for Drugs and Poisons:</td>
<td>Schedule 6</td>
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</table>

**Zaleplon**

<table>
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<th>Category</th>
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<tbody>
<tr>
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<tr>
<td>California Proposition 65</td>
<td>Not Listed</td>
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<tr>
<td>U.S. Drug Enforcement Administration:</td>
<td>Schedule IV Controlled Substance</td>
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<tr>
<td>Standard for the Uniform Scheduling for Drugs and Poisons:</td>
<td>Schedule 4</td>
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<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

WP00041
Reproductive toxicity-Cat.2; H361fd - Suspected of damaging fertility. Suspected of damaging the unborn child.
Reproductive toxicity, effects on or via lactation; H362 - May cause harm to breast-fed children

Toxic to Reproduction: Category 3
R62 - Possible risk of impaired fertility.
R63 - Possible risk of harm to the unborn child.
R64 - May cause harm to breastfed babies.

Data Sources:  
Publicly available toxicity 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.

Revision date: 25-Mar-2014
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