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

Material Name: Triazolam Tablets

<table>
<thead>
<tr>
<th>Trade Name:</th>
<th>HALCION; Semese</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical Family:</td>
<td>Mixture</td>
</tr>
<tr>
<td>Intended Use:</td>
<td>Pharmaceutical product used for insomnia.</td>
</tr>
</tbody>
</table>

2. HAZARDS IDENTIFICATION

Appearance: White, blue tablets.
Signal Word: WARNING

Statement of Hazard: Suspected of damaging the unborn child. May cause harm to breastfed babies.

Short Term: Acute toxicity following ingestion is not expected. Accidental ingestion may cause effects similar to those seen in clinical use.
Long Term: Animal studies indicate that this material may cause adverse effects on the heart, liver, lungs, central nervous system.

Known Clinical Effects: Adverse effects most commonly reported in clinical use include fatigue, clumsy motion of limbs/trunk (ataxia), state of intense good feeling (euphoria), incoordination. Other less common effects include hallucinations, delirium, amnesia, addiction, impairment of motor and cognitive skills. The effects are reversible in nature. All observed adverse effects were consistent with the sedative action of this compound. Secreted in human breast milk.

EU Indication of danger: Toxic to Reproduction: Category 2

EU Hazard Symbols: 

EU Risk Phrases: R61 - May cause harm to the unborn child.
R64 - May cause harm to breastfed babies.

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates 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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Hazardous Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Triazolam</td>
<td>28911-01-5</td>
<td>249-307-3</td>
<td>R64 Rep. Cat.2;R61</td>
<td>&lt; 77</td>
</tr>
<tr>
<td>Corn Starch</td>
<td>9005-25-8</td>
<td>232-679-6</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Microcrystalline cellulose</td>
<td>9004-34-6</td>
<td>232-674-9</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>
<tr>
<td>Silicon dioxide, NF</td>
<td>7631-86-9</td>
<td>231-545-4</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Additional Information:</th>
<th>Proprietary</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.</td>
<td></td>
</tr>
</tbody>
</table>

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: Emits toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, hydrogen chloride and other chlorine-containing compounds.
Fire Fighting Procedures: During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

Fire / Explosion Hazards: Not applicable

### 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 thoroughly after handling.

**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.

**Triazolam**

Pfizer OEL TWA-8 Hr: 0.8µg/m³

**Corn Starch**

ACGIH Threshold Limit Value (TWA) = 10 mg/m³ TWA
Australia TWA = 10 mg/m³ TWA
Belgium OEL - TWA = 10 mg/m³ TWA
Bulgaria OEL - TWA = 10.0 mg/m³ TWA
Czech Republic OEL - TWA = 4.0 mg/m³ TWA
Greece OEL - TWA = 10 mg/m³ TWA
Portugal OEL - TWA = 10 mg/m³ TWA
Spain OEL - TWA = 10 mg/m³ VLA-ED

**Microcrystalline cellulose**

ACGIH Threshold Limit Value (TWA) = 10 mg/m³ TWA
Australia TWA = 10 mg/m³ TWA
Belgium OEL - TWA = 10 mg/m³ TWA
Estonia OEL - TWA = 10 mg/m³ TWA
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:

Hands: Wear impervious gloves if skin contact is possible.

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:
10. STABILITY AND REACTIVITY

Stability: Stable at normal conditions
Conditions to Avoid: None known
Incompatible Materials: No reactions identified

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)

Lactose
Rat Oral LD50 > 10 g/kg

Sodium benzoate
Rat Oral LD50 4,070 mg/kg
Mouse Oral LD50 1600 mg/kg

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

Triazolam
Rat Oral LD50 > 5000 mg/kg
Mouse Oral LD50 > 5,000 mg/kg
Rat Intraperitoneal LD 50 > 5,000 mg/kg
Mouse Intraperitoneal LD 50 1,625 mg/kg

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

Silicon dioxide, NF
Rat Oral LD50 10 g/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

Triazolam
Eye Irritation Rabbit Mild
Skin Irritation Rabbit No effect
Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

**Sodium benzoate**
- 10 Day(s)  Rat  Oral  27370 mg/kg  LOAEL  Liver, Blood
- 10 Day(s)  Mouse  Oral  45 g/kg  LOAEL  Liver, Kidney, Blood, Ureter, Bladder

**Triazolam**
- 1 Year(s)  Dog  Oral  3 mg/kg/day  LOAEL  Central nervous system, Liver
- 1 Year(s)  Rat  Oral  1 mg/kg/day  NOAEL  Liver, Lungs, Heart
- 2 Year(s)  Rat  Oral  0.5 mg/kg/day  NOAEL  None identified
- 3 Month(s)  Dog  Oral  100 mg/kg/day  LOAEL  Central Nervous System, Liver
- 3 Month(s)  Rat  Oral  300 mg/kg/day  LOAEL  Central Nervous System

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

**Sodium benzoate**
- Embryo / Fetal Development  Rat  Oral  44 g/kg  LOEL  Developmental toxicity

**Triazolam**
- Embryo / Fetal Development  Rat  Oral  30 mg/kg/day  NOAEL  Not teratogenic
- Embryo / Fetal Development  Rabbit  Oral  30 mg/kg/day  NOAEL  Not Teratogenic
- Embryo / Fetal Development  Rabbit  Oral  5 mg/kg/day  LOAEL  Not Teratogenic, Fetotoxicity

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

**Triazolam**
- Bacterial Mutagenicity (Ames)  Bacteria  Negative
- Direct DNA Damage  Not specified  Negative

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

**Triazolam**
- 2 Year(s)  Mouse  Oral, in feed  80 NOAEL  Not carcinogenic
- 2 Year(s)  Rat  Oral, in feed  100 NOAEL  Not carcinogenic

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

Silicon dioxide, NF
- **IARC:**  Group 3

12. ECOLOGICAL INFORMATION

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

14. TRANSPORT INFORMATION

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

15. REGULATORY INFORMATION

EU Symbol: T
EU Indication of danger: Toxic to Reproduction: Category 2

EU Risk Phrases:
R61 - May cause harm to the unborn child.
R64 - May cause harm to breastfed babies.

EU Safety Phrases:
S36/37 - Wear suitable protective clothing and gloves.
S45 - In case of accident or if you feel unwell seek medical advice immediately (show the label where possible).
S53 - Avoid exposure - obtain special instructions before use.

OSHA Label:
WARNING
Suspected of damaging the unborn child.
May cause harm to breastfed babies.

Canada - WHMIS: Classifications

WHMIS hazard class:
Class D, Division 2, Subdivision A

Triazolam
California Proposition 65: developmental toxicity, initial date 4/1/90
Drug Enforcement Administration: Schedule IV
Standard for the Uniform Scheduling for Drugs and Poisons: Schedule 4
EU EINECS/ELINCS List: 249-307-3

Corn Starch
Inventory - United States TSCA - Sect. 8(b): XU

HALCION
**16. OTHER INFORMATION**

**Text of R phrases mentioned in Section 3**

R61 - May cause harm to the unborn child.
R64 - May cause harm to breastfed babies.

**Data Sources:**
Publicly available toxicity information. 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 8 - Exposure Controls / Personal Protection. Updated Section 7 - Handling and Storage.

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

### Additional Information:
US DEA Schedule IV substance

<table>
<thead>
<tr>
<th>Material</th>
<th>Inventory - United States TSCA - Sect. 8(b)</th>
<th>Australia (AICS)</th>
<th>EU EINECS/ELINCS List</th>
</tr>
</thead>
<tbody>
<tr>
<td>Microcrystalline cellulose</td>
<td>Present</td>
<td>Present</td>
<td>232-679-6</td>
</tr>
<tr>
<td>Docusate Sodium</td>
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<td>209-406-4</td>
</tr>
<tr>
<td>Lactose</td>
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<td>Present</td>
<td>200-559-2</td>
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<tr>
<td>Magnesium stearate</td>
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<td>209-150-3</td>
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<tr>
<td>Silicon dioxide, NF</td>
<td>Present</td>
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<td>231-545-4</td>
</tr>
<tr>
<td>Sodium benzoate</td>
<td>Present</td>
<td>Present</td>
<td>208-534-8</td>
</tr>
</tbody>
</table>

Australia (AICS): Present
REACH - Annex IV - Exemptions from the obligations of Register:
EU EINECS/ELINCS List 232-674-9
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