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

Material Name: Triazolam Tablets

Trade Name: HALCION; Semese
Chemical Family: Mixture
Intended Use: Pharmaceutical product used for insomnia.

2. HAZARDS IDENTIFICATION

Appearance: White, blue tablets.
Signal Word: WARNING

Statement of Hazard:
- May damage 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: T

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

2. HAZARDS IDENTIFICATION

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>EU Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Triazolam</td>
<td>28911-01-5</td>
<td>249-307-3</td>
<td>R64 Repr. Cat.2;R61</td>
<td>&lt; 77</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>Corn Starch</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>
<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>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Docusate Sodium</td>
<td>577-11-7</td>
<td>209-406-4</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Lactose</td>
<td>63-42-3</td>
<td>200-559-2</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Sodium benzoate</td>
<td>532-32-1</td>
<td>208-534-8</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: 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. 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.

Triazolam
Pfizer OEL TWA-8 Hr: 0.8µg/m³

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 - TWAs 10 mg/m³
Spain OEL - TWA 10 mg/m³
Latvia OEL - TWA 2 mg/m³
OSHA - Final PELS - TWAs: 15 mg/m³
Portugal OEL - TWA 10 mg/m³

Corn Starch
ACGIH Threshold Limit Value (TWA) 10 mg/m³
### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Material Name: Triazolam Tablets</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th><strong>Analytical Method:</strong></th>
<th>Analytical method available for triazolam. Contact Pfizer Inc for further information.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Engineering Controls:</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>Environmental Exposure Controls:</strong></td>
<td>Refer to specific Member State legislation for requirements under Community environmental legislation.</td>
</tr>
<tr>
<td><strong>Personal Protective Equipment:</strong></td>
<td>Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).</td>
</tr>
<tr>
<td><strong>Hands:</strong></td>
<td>Wear impervious gloves if skin contact is possible.</td>
</tr>
<tr>
<td><strong>Eyes:</strong></td>
<td>Wear safety glasses or goggles if eye contact is possible.</td>
</tr>
<tr>
<td><strong>Skin:</strong></td>
<td>Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.</td>
</tr>
<tr>
<td><strong>Respiratory protection:</strong></td>
<td>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.</td>
</tr>
</tbody>
</table>

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<table>
<thead>
<tr>
<th><strong>Magnesium stearate</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ACGIH Threshold Limit Value (TWA)</strong></td>
</tr>
<tr>
<td><strong>Lithuania OEL - TWA</strong></td>
</tr>
<tr>
<td><strong>Sweden OEL - TWAs</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Silicon dioxide, NF</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Australia TWA</strong></td>
</tr>
<tr>
<td><strong>Austria OEL - MAKs</strong></td>
</tr>
<tr>
<td><strong>Czech Republic OEL - TWA</strong></td>
</tr>
<tr>
<td><strong>Estonia OEL - TWA</strong></td>
</tr>
<tr>
<td><strong>Germany - TRGS 900 - TWAs</strong></td>
</tr>
<tr>
<td><strong>Germany (DFG) - MAK</strong></td>
</tr>
<tr>
<td><strong>Ireland OEL - TWAs</strong></td>
</tr>
<tr>
<td><strong>Latvia OEL - TWA</strong></td>
</tr>
<tr>
<td><strong>OSHA - Final PELs - Table Z-3 Mineral D:</strong></td>
</tr>
<tr>
<td><strong>Slovakia OEL - TWA</strong></td>
</tr>
</tbody>
</table>

| **Bulgaria OEL - TWA** | 10.0 mg/m³ |
| **Czech Republic OEL - TWA** | 4.0 mg/m³ |
| **Greece OEL - TWA** | 10 mg/m³ |
| **Ireland OEL - TWAs** | 10 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 |
| **Austria OEL - TWA** | 10 mg/m³ |
| **Czech Republic OEL - TWA** | 4 mg/m³ |
| **Greece OEL - TWA** | 4 mg/m³ |
| **Ireland OEL - TWA** | 10 mg/m³ |
| **Magazine OEL - TWA** | 10 mg/m³ |
| **Spain OEL - TWA** | 4 mg/m³ |
9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Physical State:</th>
<th>Tablet</th>
<th>Color:</th>
<th>White, blue.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Molecular Formula:</td>
<td>Mixture</td>
<td>Molecular Weight:</td>
<td>Mixture</td>
</tr>
</tbody>
</table>

10. STABILITY AND REACTIVITY

Chemical 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)

**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 LD 50 >5000 mg/kg
- Mouse Oral LD 50 > 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
11. TOXICOLOGICAL INFORMATION

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

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 (Not Classifiable)

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

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

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
May damage the unborn child.
May cause harm to breastfed babies.

Canada - WHMIS: Classifications
WHMIS hazard class:
Class D, Division 2, Subdivision A
15. REGULATORY INFORMATION

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

Microcrystalline cellulose
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- EU EINECS/ELINCS List: 232-674-9

Docusate Sodium
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- EU EINECS/ELINCS List: 209-406-4

Lactose
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- REACH - Annex IV - Exemptions from the obligations of Register: Present
- EU EINECS/ELINCS List: 200-559-2

Sodium benzoate
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- EU EINECS/ELINCS List: 208-534-8

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

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

Silicon dioxide, NF
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- EU EINECS/ELINCS List: 231-545-4

Additional Information: US DEA Schedule IV substance

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 8 - Exposure Controls / Personal Protection. Updated Section 7 - Handling and Storage. Updated Section 10 - Stability and Reactivity.

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