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

Product Identifier

Material Name: Triazolam Tablets

Trade Name: HALCION; SOMESE
Chemical Family: Mixture

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

Intended Use: Pharmaceutical product used for insomnia.

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 1B:
Effects on or via lactation

Label Elements

Signal Word: Danger
Hazard Statements: H360D - May damage 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
P260 - Do not breathe dust/fume/gas/mist/vapors/spray
P263 - Avoid contact during pregnancy/while nursing
P281 - Use personal protective equipment as required
P308 + P313 - IF exposed or concerned: Get medical attention/advice
P405 - Store locked up
Other Hazards
An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

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>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Triazolam</td>
<td>28911-01-5</td>
<td>249-307-3</td>
<td>Lact. (H362) Repr.1B (H360D)</td>
<td>0.1 - 1</td>
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<tr>
<td>Microcrystalline cellulose</td>
<td>9004-34-6</td>
<td>232-674-9</td>
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<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>
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<td>*</td>
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<tr>
<td>Silicon dioxide, NF</td>
<td>7631-86-9</td>
<td>231-545-4</td>
<td>Not Listed</td>
<td>*</td>
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</table>

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lactose</td>
<td>63-42-3</td>
<td>200-559-2</td>
<td>Not Listed</td>
<td>*</td>
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<tr>
<td>Docusate Sodium</td>
<td>577-11-7</td>
<td>209-406-4</td>
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<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. 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 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: Emits toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, hydrogen chloride and other chlorine-containing compounds.

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

Advice for Fire-Fighters
During all firefighting 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. Cleanup 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 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.

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

HALCION
### 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**

<table>
<thead>
<tr>
<th>ACGIH Threshold Limit Value (TWA)</th>
<th>10 mg/m³</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Belgium OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Estonia OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>France OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Ireland OEL - TWAs</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Latvia OEL - TWA</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>OSHA - Final PELS - TWAs:</td>
<td>15 mg/m³</td>
</tr>
<tr>
<td>Portugal OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Romania OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Russia OEL - TWA</td>
<td>6 mg/m³</td>
</tr>
<tr>
<td>Spain OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Switzerland OEL -TWAs</td>
<td>3 mg/m³</td>
</tr>
<tr>
<td>Vietnam OEL - TWAs</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td></td>
<td>5 mg/m³</td>
</tr>
</tbody>
</table>

**Corn Starch**

<table>
<thead>
<tr>
<th>ACGIH Threshold Limit Value (TWA)</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Australia TWA</td>
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</tr>
<tr>
<td>Belgium OEL - TWA</td>
<td>10 mg/m³</td>
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<td>Bulgaria OEL - TWA</td>
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<td>Czech Republic OEL - TWA</td>
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<td>Greece OEL - TWA</td>
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<tr>
<td></td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>Ireland OEL - TWAs</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td></td>
<td>4 mg/m³</td>
</tr>
<tr>
<td>OSHA - Final PELS - TWAs:</td>
<td>15 mg/m³</td>
</tr>
<tr>
<td>Portugal OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Slovakia OEL - TWA</td>
<td>4 mg/m³</td>
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<tr>
<td>Spain OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Switzerland OEL -TWAs</td>
<td>3 mg/m³</td>
</tr>
</tbody>
</table>

**Magnesium stearate**

| Lithuania OEL - TWA               | 5 mg/m³ |
| Sweden OEL - TWAs                 | 5 mg/m³ |

**Silicon dioxide, NF**

| Australia TWA                     | 2 mg/m³ |
| Austria OEL - MAKs                | 4 mg/m³ |
| Czech Republic OEL - TWA          | 0.1 mg/m³ |
|                                   | 4.0 mg/m³ |
| Estonia OEL - TWA                 | 2 mg/m³ |
| Finland OEL - TWA                 | 5 mg/m³ |
| Germany - TRGS 900 - TWAs         | 4 mg/m³ |
| Germany (DFG) - MAK               | 4 mg/m³ |
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**Analytical Method:**
Analytical method available for triazolam. Contact Pfizer Inc for further information.

**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. It is recommended that all operations be fully enclosed and no air recirculated.

Personal Protective Equipment:
Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

**Hands:**
Impervious disposable gloves (e.g. Nitrile, etc.) (double recommended) if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)

**Eyes:**
Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)

**Skin:**
Impervious disposable protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)

**Respiratory protection:**
Under normal conditions of use, 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 (e.g. particulate respirator with a full mask, P3 filter). (Respirators must meet the standards in accordance with EN136, EN143, ASTM F2704-10 or international equivalent.)

9. PHYSICAL AND CHEMICAL PROPERTIES

**Physical State:**
Tablet

**Color:**
White, blue.

**Odor:**
No data available.

**Odor Threshold:**
No data available.

**Molecular Formula:**
Mixture

**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)**

**Triazolam**
Predicted 7.4 Log D 8.175

**Lactose**
No data available

**Microcrystalline cellulose**
No data available

**Silicon dioxide, NF**

HALCION
9. PHYSICAL AND CHEMICAL PROPERTIES

No data available

Docusate Sodium
No data available

Sodium benzoate
No data available

Magnesium stearate
No data available

Corn Starch
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.

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.

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

Triazolam
11. TOXICOLOGICAL INFORMATION

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)

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

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

Sodium benzoate

Microcrystalline cellulose

Magnesium stearate

Trizolam

Embryo / Fetal Development

Sodium benzoate

Embryo / Fetal Development

HALCION
11. TOXICOLOGICAL INFORMATION

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:  See below

Silicon dioxide, NF
IARC:  Group 3 (Not Classifiable)
NTP:  Reasonably Anticipated To Be A Human Carcinogen

12. ECOLOGICAL INFORMATION

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

Toxicity:  No data available

Persistence and Degradability:  No data available

Bio-accumulative Potential:
Partition Coefficient: (Method, pH, Endpoint, Value)
Triazolam
Predicted  7.4  Log D  8.175

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.

HALCION
15. REGULATORY INFORMATION

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

Triazolam
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: developmental toxicity 4/1/1990
- 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

Lactose
- 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
- EU EINECS/ELINCS List: 200-559-2

Microcrystalline cellulose
- 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: 232-674-9

Docusate Sodium
- 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: 209-406-4

Sodium benzoate
- 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: 208-534-8

Corn Starch
15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>Regulatory Information</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>CERCLA/SARA 313 Emission reporting</td>
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<tr>
<td>California Proposition 65</td>
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<tr>
<td>Inventory - United States TSCA - Sect. 8(b)</td>
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<tr>
<td>Australia (AICS):</td>
<td>Present</td>
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<tr>
<td>REACH - Annex IV - Exemptions from the obligations of Register:</td>
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<td>EU EINECS/ELINCS List</td>
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Magnesium stearate

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<th>Regulatory Information</th>
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<tr>
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<td>Australia (AICS):</td>
<td>Present</td>
</tr>
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<td>EU EINECS/ELINCS List</td>
<td>209-150-3</td>
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</tbody>
</table>

Silicon dioxide, NF

<table>
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<tr>
<th>Regulatory Information</th>
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<tr>
<td>Inventory - United States TSCA - Sect. 8(b)</td>
<td>Present</td>
</tr>
<tr>
<td>Australia (AICS):</td>
<td>Present</td>
</tr>
<tr>
<td>EU EINECS/ELINCS List</td>
<td>231-545-4</td>
</tr>
</tbody>
</table>

Additional Information: US DEA Schedule IV substance

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3

Reproductive toxicity-Cat.1B; H360D - May damage the unborn child
Reproductive toxicity, effects on or via lactation; H362 - May cause harm to breast-fed children

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 11 - Toxicology Information.

Revision date: 26-Sep-2018
Prepared by: Product Stewardship Hazard Communication

Pfizer Inc believes that the information contained in this 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