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

<table>
<thead>
<tr>
<th>Pfizer Inc</th>
<th>Pfizer Ltd</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pfizer Pharmaceuticals Group</td>
<td>Ramsgate Road</td>
</tr>
<tr>
<td>235 East 42nd Street</td>
<td>Sandwich, Kent</td>
</tr>
<tr>
<td>New York, New York 10017</td>
<td>CT13 9NJ</td>
</tr>
<tr>
<td>1-212-573-2222</td>
<td>United Kingdom</td>
</tr>
<tr>
<td>Emergency telephone number: CHEMTREC (24 hours): 1-800-424-9300</td>
<td>Emergency telephone number: ChemSafe (24 hours): +44 (0)208 762 8322</td>
</tr>
</tbody>
</table>

Material Name: Indiplon IR Capsules

| Trade Name: | SOMPOSURE® |
| Chemical Family: | Mixture |
| Intended Use: | Pharmaceutical active used as sedative-hypnotic. |

2. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Hazardous Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS List</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indiplon</td>
<td>325715-02-4</td>
<td>Not listed</td>
<td>&lt;10</td>
</tr>
<tr>
<td>Titanium dioxide</td>
<td>13463-67-7</td>
<td>236-675-5</td>
<td>*</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>209-150-3</td>
<td>*</td>
</tr>
<tr>
<td>Starch, pregelatinized</td>
<td>9005-25-8</td>
<td>232-679-6</td>
<td>*</td>
</tr>
<tr>
<td>Silicon dioxide, colloidal NF</td>
<td>7631-86-9</td>
<td>231-545-4</td>
<td>*</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS List</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lactose NF, monohydrate</td>
<td>64044-51-5</td>
<td>Not listed</td>
<td>*</td>
</tr>
<tr>
<td>Croscarmellose sodium</td>
<td>74811-65-7</td>
<td>Not listed</td>
<td>*</td>
</tr>
<tr>
<td>FD&amp;C Blue No. 2</td>
<td>860-22-0</td>
<td>212-728-8</td>
<td>*</td>
</tr>
</tbody>
</table>

Additional Information: * Proprietary

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

3. HAZARDS IDENTIFICATION

| Appearance: | Off-white to yellow powder |
| Signal Word: | WARNING |

Statement of Hazard:

- May cause allergic reaction.
- May cause nervous system effects

Short Term:

- May cause allergic skin reaction; Not acutely toxic (based on animal data). There have been several reports of allergic-type reactions following workplace exposure to indiplon.

Known Clinical Effects:

- All observed adverse effects were consistent with the sedative action of this compound.
- Effects seen in >5% of patients included somnolence, headache, dizziness, and sedation.
- Effects seen in >1% of patients included fatigue, diplopia, nausea, abnormal gait, impaired balance, blurred vision, amnesia, and euphoria. The effects were generally mild to moderate in intensity.
**EU Indication of danger:** Irritant

**EU Hazard Symbols:**

**EU Risk Phrases:**

R43 - May cause sensitization by skin contact.

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

### 4. FIRST AID MEASURES

**Eye Contact:**

Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.

**Skin Contact:**

Remove clothing and wash affected skin with soap and water. If irritation occurs or persists, get medical attention. This material may not be completely removed by conventional laundering. Consult professional laundry service. Do not home launder.

**Ingestion:**

Get medical attention. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.

**Inhalation:**

Remove to fresh air. If not breathing, give artificial respiration. Get medical attention.

### 5. FIRE FIGHTING MEASURES

**Extinguishing Media:**

Use carbon dioxide, dry chemical, or water spray.

**Hazardous Combustion Products:**

Carbon dioxide, carbon monoxide, and oxides of nitrogen

**Fire Fighting Procedures:**

Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear.

**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: If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes.

Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Indiplon
Pfizer OEL TWA-8 Hr: 1ug/m³, Sensitizer

Titanium dioxide
OSHA - Final PELS - TWAs: = 15 mg/m³ TWA total
ACGIH Threshold Limit Value (TWA) = 10 mg/m³ TWA
Australia TWA = 10 mg/m³ TWA

Magnesium stearate
ACGIH Threshold Limit Value (TWA) = 10 mg/m³ TWA except stearates of toxic metals
Australia TWA = 10 mg/m³ TWA

Starch, pregelatinized
OSHA - Final PELS - TWAs: = 15 mg/m³ TWA total
= 5 mg/m³ TWA
ACGIH Threshold Limit Value (TWA) = 10 mg/m³ TWA
Australia TWA = 10 mg/m³ TWA

Silicon dioxide, colloidal NF
OSHA - Final PELs - Table Z-3 Mineral D: (80)/(% SiO2) mg/m³ TWA
= 20 mppcf TWA
Australia TWA = 2 mg/m³ TWA
The exposure limit(s) listed for solid components are only relevant if dust or mist may be generated.


Engineering Controls: Engineering controls should be used as the primary means to control exposures.

Personal Protective Equipment:

Hands: Not required for the normal use of this product. Wear protective gloves when working with large quantities.

Eyes: Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is possible.

Skin: Protective coveralls should be worn. The sleeves should either be taped or have gloves worn over them to prevent material from contacting the skin. Not required for the normal use of this product. Wear protective clothing when working with large quantities.

Respiratory protection: Not required for the normal use of this product. 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: Capsule
Molecular Formula: Mixture
Color: Light blue; White
Molecular Weight: Mixture
10. STABILITY AND REACTIVITY

Stability: Stable under normal conditions of use.
Conditions to Avoid: None known
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)

FD&C Blue No. 2
Rat  Oral  LD50  2 g/kg
Mouse Oral  LD50  2500 mg/kg

Titanium dioxide
Rat  Oral  LD50  > 7500 mg/kg
Rat  Subcutaneous  LD 50  50 mg/kg

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

Indiplon
Rat  Oral  LD50  > 2000 mg/kg
Rat  Dermal  LD50  > 2000 mg/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)

Indiplon
Skin Irritation  Rabbit  Negative
Eye Irritation  Rabbit  Minimal
Skin Sensitization - LLNA  Mouse  Positive

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

Indiplon
4 Week(s)  Rat  Oral  50 mg/kg/day  NOAEL  Central nervous system
4 Week(s)  Monkey  Oral  20 mg/kg/day  NOAEL  Central Nervous System
26 Week(s)  Rat  Oral  20 mg/kg/day  NOAEL  Central Nervous System

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

Indiplon
Fertility and Embryonic Development  Rat  Oral  20 mg/kg/day  NOAEL  No effects at maximum dose
Embryo / Fetal Development  Rat  Oral  20 mg/kg/day  NOAEL  Not Teratogenic
Embryo / Fetal Development  Rabbit  Oral  10 mg/kg/day  NOAEL  Maternal Toxicity, Not Teratogenic
**Genetic Toxicity: (Study Type, Cell Type/Organism, Result)**

**FD&C Blue No. 2**  
Bacterial Mutagenicity (Ames)  *Salmonella*  Negative

**Indiplon**  
Bacterial Mutagenicity (Ames)  *Salmonella*, *E. coli*  Negative  
*In Vitro* Mammalian Cell Mutagenicity  Chinese Hamster Ovary (CHO) cells  Negative  
*In Vivo* Unscheduled DNA Synthesis  Rat  Negative  
*In Vivo* Chromosome Aberration  Rat Bone Marrow  Negative  
*In Vivo* Micronucleus  Mouse  Equivocal

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

**Indiplon**  
2 Year(s)  Mouse  Oral  20 mg/kg/day  NOAEL  Not carcinogenic, Central nervous system  
2 Year(s)  Rat  Oral  20 mg/kg/day  NOAEL  Not carcinogenic, Central nervous system

Carcinogen Status:  See below

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

**Titanium dioxide**  
IARC:  Group 2B  
OSHA:  Present

**12. ECOLOGICAL INFORMATION**

Environmental Overview:  The environmental characteristics of this material have not been fully evaluated. Releases to the environment should be avoided.

**13. DISPOSAL CONSIDERATIONS**

Disposal Procedures:  Dispose of waste in accordance with all applicable laws and regulations.

**14. TRANSPORT INFORMATION**

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

**15. REGULATORY INFORMATION**

EU Symbol:  Xn
EU Indication of danger: Irritant

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

EU Safety Phrases:
S22 - Do not breathe dust.
S24 - Avoid contact with skin.
S37 - Wear suitable gloves.

OSHA Label:
WARNING
May cause allergic reaction.
May cause nervous system effects

Canada - WHMIS: Classifications

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

Lactose NF, monohydrate
Australia (AICS): Present

Croscarmellose sodium
Australia (AICS): Present
EU EINECS List 236-675-5

Titanium dioxide
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS List 231-545-4

FD&C Blue No. 2
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS List 232-679-6

Magnesium stearate
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS List 236-675-5

Starch, pregelatinized
Inventory - United States TSCA - Sect. 8(b) XU
Australia (AICS): Present
EU EINECS List 232-679-6

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

Reasons for Revision: Updated Section 2 - Composition / Information on Ingredients. Updated Section 3 - Hazard Identification. Updated Section 5 - Fire Fighting Measures. Updated Section 6 - Accidental Release Measures. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information. Updated Section 15 - Regulatory Information.

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

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 a warranty of any kind, expressed or implied.

End of Safety Data Sheet