



MATERIAL SAFETY DATA SHEET

Revision date: 04-Jan-2007

Version: 1.1

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

Pfizer Inc
Pfizer Pharmaceuticals Group
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CHEMTREC (24 hours): 1-800-424-9300

Emergency telephone number:
ChemSafe (24 hours): +44 (0)208 762 8322

Material Name: Indiplon IR Capsules

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

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

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

Ingredient	CAS Number	EU EINECS List	%
Lactose NF, monohydrate	64044-51-5	Not listed	*
Croscarmellose sodium	74811-65-7	Not listed	*
FD&C Blue No. 2	860-22-0	212-728-8	*

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.

Short Term:

May cause nervous system effects

Known Clinical Effects:

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 . 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.

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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.

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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.

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

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	Color:	Light blue; White
Molecular Formula:	Mixture	Molecular Weight:	Mixture

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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

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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

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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

Titanium dioxide

Inventory - United States TSCA - Sect. 8(b) Present

Australia (AICS): Present

EU EINECS List 236-675-5

FD&C Blue No. 2

Inventory - United States TSCA - Sect. 8(b) Present

Australia (AICS): Present

EU EINECS List 212-728-8

Magnesium stearate

Inventory - United States TSCA - Sect. 8(b) Present

Australia (AICS): Present

EU EINECS List 209-150-3

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

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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

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End of Safety Data Sheet