MATERIAL SAFETY DATA SHEET

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

Greenstone LLC
100 Route 206 North
Peapack, NJ 07977
800-435-7095

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161
Emergency telephone number:
ChemSafe (24 hours): +44 (0)208 762 8322

Material Name: Sonata (Zaleplon) Capsules

Trade Name:	SONATA
Chemical Family:	Nonbenzodiazepine pyrazolopyrimidine
Intended Use:	Pharmaceutical product used as sedative-hypnotic

2. HAZARDS IDENTIFICATION

Appearance: Green hard gelatin capsules
Signal Word: WARNING

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

Additional Hazard Information:
Long Term: Repeat-dose studies in animals have shown a potential to cause adverse effects on fertility and developing fetus.

Known Clinical Effects: Adverse effects associated with therapeutic use include abdominal pain, amnesia, dizziness, drowsiness, headache, nausea, sleepiness (somnolence), tingling sensation, allergic reaction, weakness, and may be secreted in human breast milk.

EU Indication of danger: Toxic to Reproduction: Category 3

EU Hazard Symbols:

Xn

EU Risk Phrases:

R62 - Possible risk of impaired fertility.
R63 - Possible risk of harm to the unborn child.
R64 - May cause harm to breastfed babies.

Australian Hazard Classification (NOHSC): Hazardous Substance. Non-Dangerous Goods.

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

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Microcrystalline cellulose	9004-34-6	232-674-9	Not Listed	*
Starch, pregelatinized	9005-25-8	232-679-6	Not Listed	*
Colloidal silicon dioxide	7631-86-9	231-545-4	Not Listed	*
Zaleplon	151319-34-5	Not Listed	Repr.Cat.3;R62-63-64	5 or 10mg***

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Hard gelatin capsules	MIXTURE	Not Listed	Not Listed	*
Lactose Monohydrate	64044-51-5	Not Listed	Not Listed	*
Stearic acid	57-11-4	200-313-4	Not Listed	*
Sodium lauryl sulfate	151-21-3	205-788-1	Not Listed	*

Additional Information: * Proprietary
*** per tablet/capsule/lozenge/suppository
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: Formation of toxic gases is possible during heating or fire.

Fire Fighting Procedures: During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

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

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 hands and any exposed skin after removal of PPE. 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.

Microcrystalline cellulose

ACGIH Threshold Limit Value (TWA)	10 mg/m^3 TWA
Australia TWA	10 mg/m^3
Belgium OEL - TWA	Listed
Estonia OEL - TWA	Listed
France OEL - TWA	Listed
Ireland OEL - TWAs	Listed
Latvia OEL - TWA	Listed
OSHA - Final PELS - TWAs:	15 mg/m^3 total 5 mg/m^3
Portugal OEL - TWA	Listed
Romania OEL - TWA	Listed
Spain OEL - TWA	Listed

Starch, pregelatinized

ACGIH Threshold Limit Value (TWA)	10 mg/m^3 TWA
Australia TWA	10 mg/m^3
Belgium OEL - TWA	Listed

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Bulgaria OEL - TWA	Listed
Czech Republic OEL - TWA	Listed
Greece OEL - TWA	Listed
Ireland OEL - TWAs	Listed
OSHA - Final PELS - TWAs:	15 mg/m^3 total 5 mg/m^3
Portugal OEL - TWA	Listed
Spain OEL - TWA	Listed

Colloidal silicon dioxide

Australia TWA	2 mg/m^3
Austria OEL - MAKs	Listed
Czech Republic OEL - TWA	Listed
Estonia OEL - TWA	Listed
Germany - TRGS 900 - TWAs	4 mg/m^3
Germany (DFG) - MAK	4 mg/m^3 MAK
Ireland OEL - TWAs	Listed
Latvia OEL - TWA	Listed
OSHA - Final PELs - Table Z-3 Mineral D:	- (80)/(% SiO2) mg/m^3 TWA TWA-20 mppcf
Slovenia OEL - TWA	Listed

Sodium lauryl sulfate

Pfizer OEL TWA-8 Hr:	0.3 mg/m^3

Zaleplon

Pfizer OEL TWA-8 Hr:	30µg/m^3

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.

Environmental Exposure Controls: Refer to specific Member State legislation for requirements under Community environmental legislation.

Personal Protective Equipment: Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Hands: Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

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

Physical State:	Capsule	**Color:**	Green
Molecular Formula:	Mixture	**Molecular Weight:**	Mixture

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)

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

Lactose Monohydrate
Rat Oral LD 50 29700 mg/kg

Sodium lauryl sulfate
Rat Oral LD50 1288 mg/kg

Stearic acid
Rat Oral LD50 > 4640 mg/kg
Rabbit Dermal LD50 > 5000 mg/kg

Zaleplon
Rat Oral Minimum Lethal Dose > 1000 mg/kg
Dog Oral Minimum Lethal Dose > 1000 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)

Microcrystalline cellulose
Skin Irritation Rabbit Non-irritating
Eye Irritation Rabbit Non-irritating

Sodium lauryl sulfate
Eye Irritation Rabbit Severe
Skin Irritation Rabbit Severe

Stearic acid
Skin Irritation Rabbit Moderate
Eye Irritation Rabbit Mild

Zaleplon
Eye Irritation Rabbit Non-irritating
Skin Irritation Rabbit Non-irritating

Stearic acid
30 Week(s) Rat Oral 300 ppm LOAEL Adipose tissue

11. TOXICOLOGICAL INFORMATION

Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Zaleplon
Reproductive & Fertility Rat Oral 100 mg/kg/day LOAEL Maternal toxicity, Fertility
Embryo / Fetal Development Rat Oral 10 mg/kg/day NOAEL Not Teratogenic, Developmental toxicity, Maternal Toxicity
Embryo / Fetal Development Rabbit No route specified 50 mg/kg/day NOAEL Not Teratogenic
Prenatal & Postnatal Development Rat No route specified 1 mg/kg/day NOEL Developmental toxicity

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

Lactose Monohydrate
In Vitro Bacterial Mutagenicity (Ames) Negative

Stearic acid
In Vitro Bacterial Mutagenicity (Ames) *Salmonella* Negative
Unscheduled DNA Synthesis *E. coli* Negative

Zaleplon
In Vitro Chromosome Aberration Human Lymphocytes Negative
In Vitro Bacterial Mutagenicity (Ames) *Salmonella* Negative
In Vivo Chromosome Aberration Mouse Bone Marrow Negative
In Vitro Chromosome Aberration Chinese Hamster Ovary (CHO) cells Positive
In Vivo Micronucleus Mouse Bone Marrow Negative

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

Stearic acid
26 Week(s) Rat Subcutaneous 0.5 mg/kg/week NOAEL Not carcinogenic
52 Week(s) Mouse Subcutaneous 0.05 mg/kg/week LOAEL Tumors

Zaleplon
2 Year(s) Rat Oral, in feed 20 mg/kg/day NOAEL Not carcinogenic
2 Year(s) Mouse Oral, in feed 200 mg/kg/day LOAEL Liver

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

Colloidal silicon dioxide
IARC: Group 3

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties 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: Xn
EU Indication of danger: Toxic to Reproduction: Category 3

EU Risk Phrases:

R62 - Possible risk of impaired fertility.
R63 - Possible risk of harm to the unborn child.
R64 - May cause harm to breastfed babies.

EU Safety Phrases:

S22 - Do not breathe dust.
S36/37 - Wear suitable protective clothing and gloves.

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

Canada - WHMIS: Classifications

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

Microcrystalline cellulose
Inventory - United States TSCA - Sect. 8(b) Listed

15. REGULATORY INFORMATION

Australia (AICS):	Listed
EU EINECS/ELINCS List	232-674-9

Starch, pregelatinized

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

Lactose Monohydrate

Australia (AICS):	Listed

Colloidal silicon dioxide

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	231-545-4

Stearic acid

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	200-313-4

Sodium lauryl sulfate

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	205-788-1

Zaleplon

U.S. Drug Enforcement Administration:	Schedule IV Controlled Substance

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R62 - Possible risk of impaired fertility.
R63 - Possible risk of harm to the unborn child.
R64 - May cause harm to breastfed babies.

Data Sources: Publicly available toxicity information. Safety data sheets for individual ingredients.

Prepared by: Product Stewardship Hazard Communications
Pfizer Global Environment, Health, and Safety Operations

It is believed 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. If data for a hazard are not included in this document there is no known information at this time

End of Safety Data Sheet