



MATERIAL SAFETY DATA SHEET

Revision date: 18-Nov-2010

Version: 1.1

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

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Material Name: Sildenafil Citrate Orally Disintegrating Tablet

Trade Name:	Viagra®
Chemical Family:	Mixture
Intended Use:	Pharmaceutical blend male erectile dysfunction

2. HAZARDS IDENTIFICATION

Appearance:	Blue tablets
Statement of Hazard:	Non-hazardous in accordance with international standards for workplace safety.
Additional Hazard Information: Short Term:	Active ingredient may be harmful if swallowed. May cause eye irritation (based on animal data)
Known Clinical Effects:	Ingestion of this material may cause effects similar to those seen in clinical trials including headaches, flushing, nasal congestion, penile erection, transient abnormalities in light perception and color vision, disturbed digestion (dyspepsia), and musculoskeletal aches.
EU Indication of danger:	Not classified

EU Hazard Symbols:

Australian Hazard Classification (NOHSC):	Non-Hazardous Substance. Non-Dangerous Goods.
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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.
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3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
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3. COMPOSITION/INFORMATION ON INGREDIENTS

Sildenafil citrate	171599-83-0	Not Listed	Xn;R22	14.4
Microcrystalline cellulose	9004-34-6	232-674-9	Not Listed	*
Silicon dioxide, colloidal NF	7631-86-9	231-545-4	Not Listed	*
Magnesium stearate	557-04-0	209-150-3	Not Listed	*
Artificial sweetness enhancer	NOT ASSIGNED	Not Listed	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Croscarmellose sodium	74811-65-7	Not Listed	Not Listed	*
Sucralose	56038-13-2	259-952-2	Not Listed	*
FD&C Blue No. 2	860-22-0	212-728-8	Not Listed	*
Lemon flavor	NOT ASSIGNED	Not Listed	Not Listed	*
Natural flavor	NOT ASSIGNED	Not Listed	Not Listed	*
Mannitol	69-65-8	200-711-8	Not Listed	*
Crospovidone	9003-39-8	Not Listed	Not Listed	*
Polyvinyl acetate	9003-20-7	Not Listed	Not Listed	*

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, sulfur oxides and other sulfur-containing compounds.
Fire Fighting Procedures:	Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear.
Fire / Explosion Hazards:	Fine particles (such as dust and mists) may fuel fires/explosions.

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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.

Sildenafil citrate

Pfizer OEL TWA-8 Hr:	350µg/m ³
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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

Silicon dioxide, colloidal NF

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

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Ireland OEL - TWAs	Listed
Latvia OEL - TWA	Listed
OSHA - Final PELs - Table Z-3 Mineral D:	- (80)/(% SiO ₂) mg/m ³ TWA TWA-20 mppcf
Slovenia OEL - TWA	Listed

Magnesium stearate

ACGIH Threshold Limit Value (TWA)	10 mg/m ³ TWA
Australia TWA	10 mg/m ³
Belgium OEL - TWA	Listed
Ireland OEL - TWAs	Listed
Lithuania OEL - TWA	Listed
Portugal OEL - TWA	Listed
Spain OEL - TWA	Listed
Sweden OEL - TWAs	Listed

Analytical Method:	Analytical method available for Sildenafil. Contact Pfizer Inc for further information.
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:	Tablet	Color:	Blue
Molecular Formula:	Mixture	Molecular Weight:	Mixture
Partition Coefficient (Calculated; pH 7.4 - Log D):	2.26 (Sildenafil citrate)		
Polymerization:	Will not occur		

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
Hazardous Decomposition Products:	No data available

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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

Magnesium stearate

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

FD&C Blue No. 2

Rat Oral LD50 2 g/kg
Mouse Oral LD50 2500 mg/kg

Sildenafil citrate

Rat Oral LDmin. 300-500 mg/kg
Mouse Oral LDmin. 500-1000 mg/kg
Rat Dermal LD50 > 2000 mg/kg

Mannitol

Rat Oral LD 50 13500 mg/kg
Mouse Oral LD 50 22 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

Sildenafil citrate

Eye Irritation Rabbit Moderate
Skin Irritation Rabbit Non-irritating
Skin Sensitization Guinea Pig Negative

Artificial sweetness enhancer

Eye Irritation Rabbit Mild
Skin Irritation Rabbit Mild

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

Sildenafil citrate

6 Month(s) Rat Oral 3 mg/kg/day NOAEL Adrenal gland, Liver, Thyroid
6 Month(s) Dog Oral 15 mg/kg/day NOAEL Cardiovascular system

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

Sildenafil citrate

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11. TOXICOLOGICAL INFORMATION

Reproductive & Fertility	Rat	Oral	60 mg/kg/day	NOEL	No effects at maximum dose
Embryo / Fetal Development	Rat	Oral	50 mg/kg/day	NOEL	Maternal Toxicity, Not Teratogenic
Embryo / Fetal Development	Rabbit	Oral	50 mg/kg/day	NOEL	Maternal Toxicity, Not Teratogenic

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

FD&C Blue No. 2

Bacterial Mutagenicity (Ames) *Salmonella* Negative

Sildenafil citrate

In Vitro Bacterial Mutagenicity (Ames) *Salmonella* Negative

In Vitro Cytogenetics Human Lymphocytes Negative

In Vivo Micronucleus Chromosome Aberration Mouse Bone Marrow Negative

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

Sildenafil citrate

24 Month(s) Mouse Oral 5 mg/kg/day NOAEL Not carcinogenic

24 Month(s) Rat Oral 60 mg/kg/day NOAEL Not carcinogenic

Carcinogen Status:

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

Silicon dioxide, colloidal NF

IARC: Group 3

Crospovidone

IARC: Group 3

Polyvinyl acetate

IARC: Group 3

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties of the formulation have not been thoroughly investigated. The following information is available for the individual ingredients.

**Partition Coefficient
(Calculated; pH 7.4 - Log D):** 2.26 (Sildenafil citrate)

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

Sildenafil citrate

Daphnia magna (Water Flea) TAD EC50 48 Hours 14 mg/L

Oncorhynchus mykiss (Rainbow Trout) OECD LC50 96 Hours > 9.5 mg/L

Pseudokirchneriella subcapitata (Green Alga) OECD EC50 72 Hours 20 mg/L

Aquatic Toxicity Comments: A greater than symbol (>) indicates that aquatic toxicity was not observed at the maximum dose tested.

Bacterial Inhibition: (Inoculum, Method, End Point, Result)

Sildenafil citrate

Activated sludge OECD EC50 3 Hours > 1000 mg/L

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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

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

15. REGULATORY INFORMATION

EU Indication of danger: Not classified

EU Safety Phrases: S57 - Use appropriate containment to avoid environmental contamination.

OSHA Label:
Non-hazardous in accordance with international standards for workplace safety.

Canada - WHMIS: Classifications

WHMIS hazard class:
Class D, Division 1, Subdivision B



Croscarmellose sodium	
Australia (AICS):	Listed
Microcrystalline cellulose	
Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	232-674-9
Sucralose	
Australia (AICS):	Listed
EU EINECS/ELINCS List	259-952-2

FD&C Blue No. 2

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15. REGULATORY INFORMATION

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	212-728-8
Silicon dioxide, colloidal NF	
Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	231-545-4
Magnesium stearate	
Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	209-150-3
Mannitol	
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	200-711-8
Crospovidone	
Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
Polyvinyl acetate	
Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R22 - Harmful if swallowed.

Data Sources: Safety data sheets for individual ingredients. Pfizer proprietary drug development information.

Reasons for Revision: Updated Section 3 - Composition / Information on Ingredients.

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

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End of Safety Data Sheet