



# SAFETY DATA SHEET

Revision date: 06-Apr-2015

Version: 2.0

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

### Product Identifier

**Material Name:** Sildenafil Citrate Orally Disintegrating Tablet

**Trade Name:** Viagra®

**Chemical Family:** Mixture

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

**Intended Use:** Pharmaceutical blend male erectile dysfunction

### 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  
**Contact E-Mail:** pfizer-MSDS@pfizer.com

**Emergency telephone number:**  
**International CHEMTREC (24 hours):** +1-703-527-3887

## 2. HAZARDS IDENTIFICATION

### Classification of the Substance or Mixture

#### GHS - Classification

Serious Eye Damage/Eye Irritation: Category 2B

#### EU Classification:

EU Indication of danger: Not classified

### Label Elements

**Signal Word:** Warning

**Hazard Statements:** H320 - Causes eye irritation

#### Precautionary Statements:

P264 - Wash hands thoroughly after handling  
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing  
P337 + P313 - If eye irritation persists: Get medical advice/attention

#### Other Hazards

No data available

#### Australian Hazard Classification (NOHSC):

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.

### 3. COMPOSITION / INFORMATION ON INGREDIENTS

#### Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Silicon dioxide, colloidal NF	7631-86-9	231-545-4	Not Listed	Not Listed	*
Artificial sweetness enhancer	NOT ASSIGNED	Not Listed	Not Listed	Not Listed	*
Sildenafil citrate	171599-83-0	Not Listed	Xn;R22	Acute Tox.4 (H302) Eye Irrit.2B (H320) Aquatic Acute 3 (H402) Aquatic Chronic 3 (H412)	14.4
Magnesium stearate	557-04-0	209-150-3	Not Listed	Not Listed	*
Microcrystalline cellulose	9004-34-6	232-674-9	Not Listed	Not Listed	*

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

**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 R phrases and 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.

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**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:** Use carbon dioxide, dry chemical, or water spray.

### Special Hazards Arising from the Substance or Mixture

**Hazardous Combustion Products:** Emits toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, sulfur oxides and other sulfur-containing compounds.

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

### Advice for Fire-Fighters

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

## 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. Clean up 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 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.

### 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

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Refer to available public information for specific member state Occupational Exposure Limits.

#### Silicon dioxide, colloidal NF

Australia TWA	2 mg/m <sup>3</sup>
Austria OEL - MAKs	4 mg/m <sup>3</sup>
	0.3 mg/m <sup>3</sup>
Czech Republic OEL - TWA	0.1 mg/m <sup>3</sup>
	4.0 mg/m <sup>3</sup>
Estonia OEL - TWA	2 mg/m <sup>3</sup>
Finland OEL - TWA	5 mg/m <sup>3</sup>
Germany - TRGS 900 - TWAs	4 mg/m <sup>3</sup>
Germany (DFG) - MAK	4 mg/m <sup>3</sup>
Ireland OEL - TWAs	6 mg/m <sup>3</sup>
	2.4 mg/m <sup>3</sup>
Latvia OEL - TWA	1 mg/m <sup>3</sup>
OSHA - Final PELs - Table Z-3 Mineral D:	20 mppcf
	Listed
Slovakia OEL - TWA	4.0 mg/m <sup>3</sup>
Switzerland OEL - TWAs	4 mg/m <sup>3</sup>
	0.3 mg/m <sup>3</sup>

#### Sildenafil citrate

Pfizer OEL TWA-8 Hr:	350µg/m <sup>3</sup>
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#### Magnesium stearate

ACGIH Threshold Limit Value (TWA)	10 mg/m <sup>3</sup>
Lithuania OEL - TWA	5 mg/m <sup>3</sup>
Sweden OEL - TWAs	5 mg/m <sup>3</sup>

#### Microcrystalline cellulose

ACGIH Threshold Limit Value (TWA)	10 mg/m <sup>3</sup>
Australia TWA	10 mg/m <sup>3</sup>
Belgium OEL - TWA	10 mg/m <sup>3</sup>
Estonia OEL - TWA	10 mg/m <sup>3</sup>
France OEL - TWA	10 mg/m <sup>3</sup>
Ireland OEL - TWAs	10 mg/m <sup>3</sup>
	4 mg/m <sup>3</sup>
Latvia OEL - TWA	2 mg/m <sup>3</sup>
OSHA - Final PELs - TWAs:	15 mg/m <sup>3</sup>
Portugal OEL - TWA	10 mg/m <sup>3</sup>
Romania OEL - TWA	10 mg/m <sup>3</sup>
Russia OEL - TWA	6 mg/m <sup>3</sup>
Spain OEL - TWA	10 mg/m <sup>3</sup>
Switzerland OEL - TWAs	3 mg/m <sup>3</sup>
Vietnam OEL - TWAs	10 mg/m <sup>3</sup>
	5 mg/m <sup>3</sup>

#### Analytical Method:

Analytical method available for Sildenafil. 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.

##### Personal Protective Equipment:

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

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**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

<b>Physical State:</b>	Tablet	<b>Color:</b>	Blue
<b>Odor:</b>	No data available.	<b>Odor Threshold:</b>	No data available.
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	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)**

**Microcrystalline cellulose**

No data available

**Magnesium stearate**

No data available

**Croscarmellose sodium**

No data available

**Sucralose**

No data available

**FD&C Blue No. 2**

No data available

**Silicon dioxide, colloidal NF**

No data available

**Sildenafil citrate**

Predicted 7.4 Log D 2.26

**Artificial sweetness enhancer**

No data available

**Lemon flavor**

No data available

**Natural flavor**

No data available

**Mannitol**

No data available

**Crospovidone**

No data available

**Polyvinyl acetate**

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

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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

Polymerization: Will not occur

## 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:** 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.

### 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/m <sup>3</sup>

#### FD&C Blue No. 2

Rat	Oral	LD50	2 g/kg
Mouse	Oral	LD50	2500mg/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
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### 11. TOXICOLOGICAL INFORMATION

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

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

##### **Sildenafil citrate**

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

#### **Carcinogen Status:**

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

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### 11. TOXICOLOGICAL INFORMATION

#### Silicon dioxide, colloidal NF

IARC: Group 3 (Not Classifiable)

#### Crospovidone

IARC: Group 3 (Not Classifiable)

#### Polyvinyl acetate

IARC: Group 3 (Not Classifiable)

### 12. ECOLOGICAL INFORMATION

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

#### Toxicity:

#### 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 > 1000 mg/L

**Persistence and Degradability:** No data available

#### **Bio-accumulative Potential:**

#### **Partition Coefficient: (Method, pH, Endpoint, Value)**

##### Sildenafil citrate

Predicted 7.4 Log D 2.26

**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.



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### 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

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

#### Canada - WHMIS: Classifications

WHMIS hazard class:

Class D, Division 1, Subdivision B



#### Sucralose

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	259-952-2

#### FD&C Blue No. 2

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	212-728-8

#### Silicon dioxide, colloidal NF

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	231-545-4

#### Lemon flavor

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

#### Artificial sweetness enhancer

CERCLA/SARA 313 Emission reporting	Not Listed
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**15. REGULATORY INFORMATION**

California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed
<b>Natural flavor</b>	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed
<b>Mannitol</b>	
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	200-711-8
<b>Crospovidone</b>	
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	Not Listed
<b>Croscarmellose sodium</b>	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	Not Listed
<b>Sildenafil citrate</b>	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed
<b>Magnesium stearate</b>	
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	209-150-3
<b>Microcrystalline cellulose</b>	
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 XVII - Restrictions on Certain Dangerous Substances:	Use restricted. See item 9[f]. powder
EU EINECS/ELINCS List	232-674-9
<b>Polyvinyl acetate</b>	

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### 15. REGULATORY INFORMATION

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	Not Listed

### 16. OTHER INFORMATION

#### Text of R phrases and GHS Classification abbreviations mentioned in Section 3

Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed  
Serious eye damage/eye irritation-Cat. 2B; H320 - Causes eye irritation  
Hazardous to the aquatic environment, acute toxicity-Cat.3; H402 - Harmful to aquatic life  
Hazardous to the aquatic environment, chronic toxicity-Cat.3; H412 - Harmful to aquatic life with long lasting effects

Xn - Harmful

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. Updated Section 2 - Hazard Identification. Updated Section 7 - Handling and Storage. Updated Section 12 - Ecological Information. Updated Section 11 - Toxicology Information. Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 16 - Other Information.

**Revision date:** 06-Apr-2015  
Product Stewardship Hazard Communication

**Prepared by:** Pfizer Global Environment, Health, and Safety Operations

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 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**