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

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


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

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>PZ01280</td>
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<td></td>
<td></td>
<td></td>
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</table>
3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sildenafil citrate</td>
<td>171599-83-0</td>
<td>Not Listed</td>
<td>Xn;R22</td>
<td>14.4</td>
</tr>
<tr>
<td>Microcrystalline cellulose</td>
<td>9004-34-6</td>
<td>232-674-9</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Silicon dioxide, colloidal NF</td>
<td>7631-86-9</td>
<td>231-545-4</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>209-150-3</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Artificial sweetness enhancer</td>
<td>NOT ASSIGNED</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Croscarmellose sodium</td>
<td>74811-65-7</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Sucralose</td>
<td>56038-13-2</td>
<td>259-952-2</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>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Lemon flavor</td>
<td>NOT ASSIGNED</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Natural flavor</td>
<td>NOT ASSIGNED</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Mannitol</td>
<td>69-65-8</td>
<td>200-711-8</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Crospovidone</td>
<td>9003-39-8</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Polyvinyl acetate</td>
<td>9003-20-7</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

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.
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/m³

Microcrystalline cellulose
- ACGIH Threshold Limit Value (TWA): 10 mg/m³ TWA
- Australia TWA: 10 mg/m³
- 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/m³ total
- Portugal OEL - TWA: Listed
- Romania OEL - TWA: Listed
- Spain OEL - TWA: Listed

Silicon dioxide, colloidal NF
- Australia TWA: 2 mg/m³
- Austria OEL - MAKs: Listed
- Czech Republic OEL - TWA: Listed
- Estonia OEL - TWA: Listed
- Germany - TRGS 900 - TWAs: 4 mg/m³
- Germany (DFG) - MAK: 4 mg/m³ MAK
8. EXPOSURE CONTROLS / PERSONAL PROTECTION


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
- Molecular Formula: Mixture
- Partition Coefficient: 2.26 (Sildenafil citrate)
- Molecular Weight: Mixture
- Color: Blue

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
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)**

<table>
<thead>
<tr>
<th>Substance</th>
<th>Species</th>
<th>Route</th>
<th>End Point</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Microcrystalline cellulose</td>
<td>Rat</td>
<td>Oral</td>
<td>LD50</td>
<td>&gt; 5000 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Rabbit</td>
<td>Dermal</td>
<td>LD50</td>
<td>&gt; 2000 mg/kg</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>Rat</td>
<td>Oral</td>
<td>LD50</td>
<td>&gt; 2000 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Rat</td>
<td>Inhalation</td>
<td>LC50</td>
<td>&gt; 2000 mg/m³</td>
</tr>
<tr>
<td>FD&amp;C Blue No. 2</td>
<td>Rat</td>
<td>Oral</td>
<td>LD50</td>
<td>2 g/kg</td>
</tr>
<tr>
<td></td>
<td>Mouse</td>
<td>Oral</td>
<td>LD50</td>
<td>2500 mg/kg</td>
</tr>
<tr>
<td>Sildenafil citrate</td>
<td>Rat</td>
<td>Oral</td>
<td>LD min.</td>
<td>300-500 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Mouse</td>
<td>Oral</td>
<td>LD min.</td>
<td>500-1000 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Rat</td>
<td>Dermal</td>
<td>LD50</td>
<td>&gt; 2000 mg/kg</td>
</tr>
<tr>
<td>Mannitol</td>
<td>Rat</td>
<td>Oral</td>
<td>LD 50</td>
<td>13500 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Mouse</td>
<td>Oral</td>
<td>LD 50</td>
<td>22 g/kg</td>
</tr>
</tbody>
</table>

**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)**

<table>
<thead>
<tr>
<th>Substance</th>
<th>Study Type</th>
<th>Species</th>
<th>Route</th>
<th>Severity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Microcrystalline cellulose</td>
<td>Skin</td>
<td>Rabbit</td>
<td></td>
<td>Non-irritating</td>
</tr>
<tr>
<td></td>
<td>Eye</td>
<td>Rabbit</td>
<td></td>
<td>Non-irritating</td>
</tr>
<tr>
<td>Sildenafil citrate</td>
<td>Eye</td>
<td>Rabbit</td>
<td></td>
<td>Moderate</td>
</tr>
<tr>
<td></td>
<td>Skin</td>
<td>Rabbit</td>
<td></td>
<td>Non-irritating</td>
</tr>
<tr>
<td></td>
<td>Skin Sensitization</td>
<td>Guinea Pig</td>
<td></td>
<td>Negative</td>
</tr>
<tr>
<td>Artificial sweetness enhancer</td>
<td>Eye</td>
<td>Rabbit</td>
<td></td>
<td>Mild</td>
</tr>
<tr>
<td></td>
<td>Skin</td>
<td>Rabbit</td>
<td></td>
<td>Mild</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Substance</th>
<th>Duration</th>
<th>Species</th>
<th>Route</th>
<th>Dose</th>
<th>End Point</th>
<th>Target Organ</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sildenafil citrate</td>
<td>6 Month(s)</td>
<td>Rat</td>
<td>Oral</td>
<td>3 mg/kg/day</td>
<td>NOAEL</td>
<td>Adrenal gland, Liver, Thyroid</td>
</tr>
<tr>
<td></td>
<td>6 Month(s)</td>
<td>Dog</td>
<td>Oral</td>
<td>15 mg/kg/day</td>
<td>NOAEL</td>
<td>Cardiovascular system</td>
</tr>
</tbody>
</table>

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

Sildenafil citrate
11. TOXICOLOGICAL INFORMATION

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.

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
- *Onchorhynchus 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
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

Crocarmellose 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
15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>Material</th>
<th>United States TSCA - Sect. 8(b)</th>
<th>Australia (AICS)</th>
<th>EU EINECS/ELINCS List</th>
</tr>
</thead>
<tbody>
<tr>
<td>Silicon dioxide, colloidal NF</td>
<td>Listed</td>
<td>Listed</td>
<td>212-728-8</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>Listed</td>
<td>Listed</td>
<td>231-545-4</td>
</tr>
<tr>
<td>Mannitol</td>
<td>Listed</td>
<td>Listed</td>
<td>209-150-3</td>
</tr>
<tr>
<td>Crospovidone</td>
<td>Listed</td>
<td>Listed</td>
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</tr>
<tr>
<td>Polyvinyl acetate</td>
<td>Listed</td>
<td>Listed</td>
<td></td>
</tr>
</tbody>
</table>

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

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