SAFETY DATA SHEET

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

Product Identifier

Material Name: AVIGRA (Sildenafil Citrate) Tablets
Trade Name: AVIGRA
Synonyms: Sildenafil citrate tablets
Chemical Family: Mixture

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

Intended Use: Pharmaceutical product used for 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:
1-877-777-3180
Contact E-Mail: pfizer-MSDS@pfizer.com

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
Australian Hazard Classification (NOHSC):
No data available
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>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Microcrystalline cellulose</td>
<td>9004-34-6</td>
<td>232-674-9</td>
<td>Not Listed</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>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Sildenafil citrate</td>
<td>171599-83-0</td>
<td>Not Listed</td>
<td>Xn,R22</td>
<td>Acute Tox.4 (H302)</td>
<td>23</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Eye Irrit.2B (H320)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Aquatic Acute 3</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(H402)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Aquatic Chronic 3</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(H412)</td>
<td></td>
</tr>
<tr>
<td>Titanium dioxide</td>
<td>13463-67-7</td>
<td>236-675-5</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
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</tbody>
</table>

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.

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Most Important Symptoms and Effects, Both Acute and Delayed
SAFETY DATA SHEET

Material Name: AVIGRA (Sildenafil Citrate) Tablets
Revision date: 05-Sep-2014

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: Extinguish fires with CO2, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture
Hazardous Combustion Products:
Formation of toxic gases is possible during heating or fire.

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

Advice for Fire-Fighters
During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

Additional Information: Not applicable

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 thoroughly after handling. 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. Refer to Section 12 - Ecological Information, for information on potential effects on the environment.

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
### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

**Calcium phosphate dibasic, anhydrous**

<table>
<thead>
<tr>
<th>Country</th>
<th>OEL - TWA</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Latvia OEL - TWA</td>
<td>10 mg/m³</td>
<td></td>
</tr>
</tbody>
</table>

**Microcrystalline cellulose**

<table>
<thead>
<tr>
<th>Source</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACGIH Threshold Limit Value (TWA)</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Australia TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Belgium OEL - TWA</td>
<td>10 mg/m³</td>
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<tr>
<td>Estonia OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>France OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Ireland OEL - TWAs</td>
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<tr>
<td>Latvia OEL - TWA</td>
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<tr>
<td>OSHA - Final PELs - TWAs:</td>
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</tr>
<tr>
<td>Portugal OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Romania OEL - TWA</td>
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</tr>
<tr>
<td>Russia OEL - TWA</td>
<td>6 mg/m³</td>
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<tr>
<td>Spain OEL - TWA</td>
<td>10 mg/m³</td>
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<tr>
<td>Switzerland OEL - TWAs</td>
<td>3 mg/m³</td>
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**Magnesium stearate**

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<th>Source</th>
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<tr>
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<td>10 mg/m³</td>
</tr>
<tr>
<td>Lithuania OEL - TWA</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>Sweden OEL - TWAs</td>
<td>5 mg/m³</td>
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</table>

**Sildenafil citrate**

<table>
<thead>
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<th>Source</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pfizer OEL TWA-8 Hr:</td>
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</table>

**Titanium dioxide**

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<th>Value</th>
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</thead>
<tbody>
<tr>
<td>ACGIH Threshold Limit Value (TWA)</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>ACGIH OELs - Notice of Intended Changes Listed</td>
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</tr>
<tr>
<td>Australia TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Austria OEL - MAKs</td>
<td>5 mg/m³</td>
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<tr>
<td>Belgium OEL - TWA</td>
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<tr>
<td>Bulgaria OEL - TWA</td>
<td>10.0 mg/m³</td>
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<td>Denmark OEL - TWA</td>
<td>6 mg/m³</td>
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<tr>
<td>Estonia OEL - TWA</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>France OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Greece OEL - TWA</td>
<td>10 mg/m³</td>
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<tr>
<td></td>
<td>5 mg/m³</td>
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<tr>
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<td></td>
<td>4 mg/m³</td>
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<tr>
<td>Latvia OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Lithuania OEL - TWA</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>OSHA - Final PELs - TWAs:</td>
<td>15 mg/m³</td>
</tr>
<tr>
<td>Poland OEL - TWA</td>
<td>10.0 mg/m³</td>
</tr>
<tr>
<td>Portugal OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Romania OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Russia OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
</tbody>
</table>
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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:

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

Odor: No data available.

Molecular Formula: 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)

Calcium phosphate dibasic, anhydrous

No data available

Microcrystalline cellulose

No data available

Magnesium stearate

No data available

Croscarmellose sodium

No data available

Sildenafil citrate

Predicted 7.4 Log D 2.26

Hydroxypropyl methylcellulose

No data available

Titanium dioxide

No data available

Lactose Monohydrate

No data available

Triacetin

No data available

FD & C Blue No. 2, Aluminum lake

No data available
9. PHYSICAL AND CHEMICAL PROPERTIES

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
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

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: None known
- 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 components).

Long Term: Animal studies indicate that this material may cause adverse effects on the cardiovascular system.

Known Clinical Effects: Adverse effects most commonly reported in clinical use include difficult digestion (dyspepsia), nose bleed, headache, flushing, insomnia, abnormal redness of skin (erythema), difficulty breathing, muscle pain, fever, gastrointestinal irritation, tingling/itching (paresthesia), transient changes in light perception and color vision, effects on hearing, and effects on vision.

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

Sildenafil citrate
- Rat Oral LDmin. 300-500 mg/kg
- Mouse Oral LDmin. 500-1000 mg/kg
## 11. TOXICOLOGICAL INFORMATION

### 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.

<table>
<thead>
<tr>
<th>Material Name</th>
<th>Study Type</th>
<th>Species</th>
<th>Route</th>
<th>Dose</th>
<th>End Point</th>
<th>Target Organ</th>
</tr>
</thead>
<tbody>
<tr>
<td>Triacetin</td>
<td>Oral</td>
<td>Rat</td>
<td>LD50</td>
<td>&gt; 10,000 mg/kg</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lactose Monohydrate</td>
<td>Oral</td>
<td>Rat</td>
<td>LD 50</td>
<td>29700 mg/kg</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hydroxypropyl methylcellulose</td>
<td>Oral</td>
<td>Rat</td>
<td>LD50</td>
<td>&gt; 2000 mg/kg</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Titanium dioxide</td>
<td>Oral</td>
<td>Rat</td>
<td>LD50</td>
<td>&gt; 7500 mg/kg</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lactose Monohydrate</td>
<td>Subcutaneous</td>
<td>Rat</td>
<td>LD50</td>
<td>50 mg/kg</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### 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

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

- **Sildenafil citrate**
  - 6 Month(s) Rat Oral LD50 3000 mg/kg
  - 6 Month(s) Dog Oral LD50 15 mg/kg/day

### 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)

- **Sildenafil citrate**
  - *In Vitro* Bacterial Mutagenicity (Ames) *Salmonella* Negative
  - *In Vitro* Cytogenetics Human Lymphocytes Negative
  - *In Vivo* Micronucleus Chromosome Aberration Mouse Bone Marrow Negative

- **Lactose Monohydrate**
  - *In Vitro* Bacterial Mutagenicity (Ames) Negative
11. TOXICOLOGICAL INFORMATION

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 present in this material at concentrations equal to or greater than 0.1% are listed by IARC, NTP, OSHA, or ACGIH as a carcinogen.

**Titanium dioxide**
- **IARC:** Group 2B (Possibly Carcinogenic to Humans)

12. ECOLOGICAL INFORMATION

**Environmental Overview:** In the environment, the active ingredient in this formulation is expected to remain in water or migrate through the soil to groundwater.

**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 acute ecotoxicity was not observed at the maximum solubility. Since the substance is insoluble in aqueous solutions above this concentration, an acute ecotoxicity value (i.e. LC/EC50) is not achievable.

**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.

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:
None required
This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all of the information required by the CPR.

FD & C Blue No. 2, Aluminum lake
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 240-589-3

Lactose Monohydrate
CERCLA/SARA 313 Emission reporting Not Listed
California Proposition 65 Not Listed
Australia (AICS): Present
REACH - Annex IV - Exemptions from the obligations of Register: Present
EU EINECS/ELINCS List Not Listed

Triacetin
CERCLA/SARA 313 Emission reporting Not Listed
California Proposition 65 Not Listed
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
## 15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>Material</th>
<th>EU EINECS/ELINCS List</th>
<th>California Proposition 65</th>
<th>California Proposition 65</th>
<th>Inventory - United States TSCA - Sect. 8(b)</th>
<th>Australia (AICS):</th>
<th>Standard for the Uniform Scheduling for Drugs and Poisons:</th>
<th>REACH - Annex XVII - Restrictions on Certain Dangerous Substances:</th>
<th>EU EINECS/ELINCS List</th>
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<tbody>
<tr>
<td>Hydroxypropyl methylcellulose</td>
<td>203-051-9</td>
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<td>Not Listed</td>
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<td>Schedule 4</td>
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<tr>
<td>Microcrystalline cellulose</td>
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<td>Present</td>
<td>Present</td>
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<td>Use restricted. See item 9[f], powder</td>
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<tr>
<td>Magnesium stearate</td>
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<td>Not Listed</td>
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<td>Present</td>
<td>Present</td>
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<td></td>
<td>209-150-3</td>
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<td>Sildenafil citrate</td>
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<td>Not Listed</td>
<td>Not Listed</td>
<td>Present</td>
<td>Present</td>
<td></td>
<td></td>
<td>236-675-5</td>
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<td>Titanium dioxide</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>236-675-5</td>
</tr>
</tbody>
</table>
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:
Pfizer proprietary drug development information. Safety data sheets for individual ingredients.

Reasons for Revision:
Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking.
Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 4 - First Aid Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information. Updated Section 15 - Regulatory Information. Updated Section 16 - Other Information.

Revision date:
05-Sep-2014
Prepared by:
Product Stewardship Hazard Communication
Pfizer Global Environment, Health, and Safety Operations

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End of Safety Data Sheet