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

Material Name: AVIGRA (Sildenafil Citrate) Tablets

  Trade Name: Viagra®
  Synonyms: Sildenafil citrate tablets
  Chemical Family: Mixture
  Intended Use: Pharmaceutical product used for male erectile dysfunction

2. HAZARDS IDENTIFICATION

Appearance: Blue film-coated 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 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.

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>Sildenafil citrate</td>
<td>171599-83-0</td>
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<td>Xn;R22</td>
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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>Microcrystalline cellulose</td>
<td>9004-34-6</td>
<td>232-674-9</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Titanium dioxide</td>
<td>13463-67-7</td>
<td>236-675-5</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>FD &amp; C Blue No. 2, Aluminum lake</td>
<td>16521-38-3</td>
<td>240-589-3</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Lactose Monohydrate</td>
<td>64044-51-5</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Triacetin</td>
<td>102-76-1</td>
<td>203-051-9</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Calcium phosphate dibasic, anhydrous</td>
<td>7757-93-9</td>
<td>231-826-1</td>
<td>Not Listed</td>
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<tr>
<td>Croscarmellose sodium</td>
<td>74811-65-7</td>
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<tr>
<td>Hydroxypropyl methylcellulose</td>
<td>9004-65-3</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: Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.

Skin Contact: Wash skin with soap and water. Remove contaminated clothing and shoes. If irritation occurs or persists, get medical attention. This material may not be completely removed by conventional laundering. Consult professional laundry service. Do not home launder.

Ingestion: Get medical attention immediately. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.

Inhalation: Remove to fresh air. If not breathing, give artificial respiration. Get 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.

Additional Information: Not applicable

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 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.

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.

Calcium phosphate dibasic, anhydrous
- Latvia OEL - TWA 10 mg/m³

Sildenafil citrate
- Pfizer OEL TWA-8 Hr: 350µg/m³

Microcrystalline cellulose
- ACGIH Threshold Limit Value (TWA) 10 mg/m³
- Australia TWA 10 mg/m³
- Belgium OEL - TWA 10 mg/m³
- Estonia OEL - TWA 10 mg/m³
- France OEL - TWA 10 mg/m³
- Ireland OEL - TWAs 10 mg/m³
- Latvia OEL - TWA 4 mg/m³
- OSHA - Final PELS - TWAs: 2 mg/m³
- Portugal OEL - TWA 10 mg/m³
- Romania OEL - TWA 10 mg/m³
- Spain OEL - TWA 10 mg/m³

Titanium dioxide
- ACGIH Threshold Limit Value (TWA) 10 mg/m³
- Australia TWA 10 mg/m³
- Austria OEL - MAKs 5 mg/m³
- Belgium OEL - TWA 10 mg/m³
- Bulgaria OEL - TWA 10.0 mg/m³
- Denmark OEL - TWA 6 mg/m³
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
- Color: Blue
- Molecular Weight: Mixture

10. STABILITY AND REACTIVITY

- Chemical Stability: Stable under normal conditions of use.
- Conditions to Avoid: None known
- 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

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
Rat Dermal LD50 > 2000 mg/kg

Hydroxypropyl methylcellulose
Rat Oral LD50 > 10,000 mg/kg

Titanium dioxide
Rat Oral LD50 > 7500 mg/kg
Rat Subcutaneous LD 50 50 mg/kg

Lactose Monohydrate
Rat Oral LD 50 29700 mg/kg

Triacetin
Rat Oral LD 50 3000 mg/kg
Mouse Oral LD 50 1100 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

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 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))
11. TOXICOLOGICAL INFORMATION

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

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)
OSHA:  Listed

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.

Mobility, Persistence and Degradability:  The active ingredient in this formulation is water soluble and is expected to remain primarily in water.

Bioaccumulation and Toxicity:  The active ingredient in this formulation has low potential to bioaccumulate and long-term adverse effects to aquatic organisms are not expected. See aquatic toxicity data, below.

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  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

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 Indication of danger: Not classified

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

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
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS/ELINCS List 240-589-3

Lactose Monohydrate
Australia (AICS): Present

Triacetin
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS/ELINCS List 203-051-9

Calcium phosphate dibasic, anhydrous
15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>Material Name</th>
<th>Inventory - United States TSCA - Sect. 8(b)</th>
<th>Australia (AICS):</th>
<th>EU EINECS/ELINCS List</th>
</tr>
</thead>
<tbody>
<tr>
<td>Croscarmellose sodium</td>
<td>Present</td>
<td>Present</td>
<td>231-826-1</td>
</tr>
<tr>
<td>Hydroxypropyl methylcellulose</td>
<td>Present</td>
<td>Present</td>
<td></td>
</tr>
<tr>
<td>Microcrystalline cellulose</td>
<td>Present</td>
<td>Present</td>
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</tr>
<tr>
<td>Magnesium stearate</td>
<td>Present</td>
<td>Present</td>
<td>209-150-3</td>
</tr>
</tbody>
</table>

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R22 - Harmful if swallowed.

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

Prepared by: Product Stewardship Hazard Communication
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