SAFETY DATA SHEET

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

Product Identifier
Material Name: Sildenafil Citrate Powder for Oral Solution
Trade Name: Revatio
Synonyms: Sildenafil Citrate Powder for Oral Solution; REVATIO POS
Chemical Family: Mixture

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against
Intended Use: Pharmaceutical product used for Treatment of pulmonary arterial hypertension

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
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 Not classified as hazardous
US OSHA Specific - Classification
Physical Hazard: Combustible Dust
EU Classification:
EU Indication of danger: Not classified

Label Elements
Hazard Statements: May form combustible dust concentrations in air

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

#### Hazardous

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>GHS Classification</th>
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<tbody>
<tr>
<td>Citric acid</td>
<td>77-92-9</td>
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<td></td>
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<td>Aquatic Acute 3</td>
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<td>(H402)</td>
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<td>236-675-5</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 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**

**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**
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: 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.

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

Colloidal silicon dioxide

<table>
<thead>
<tr>
<th>Country</th>
<th>Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia TWA</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Austria OEL - MAKs</td>
<td>4 mg/m³</td>
</tr>
<tr>
<td></td>
<td>0.3 mg/m³</td>
</tr>
<tr>
<td>Czech Republic OEL - TWA</td>
<td>0.1 mg/m³</td>
</tr>
<tr>
<td></td>
<td>4.0 mg/m³</td>
</tr>
</tbody>
</table>

PZ00976
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.

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.

<table>
<thead>
<tr>
<th>Country/Region</th>
<th>OEL - TWAs</th>
<th>OEL - TWAs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Estonia OEL - TWA</td>
<td>2 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Finland OEL - TWA</td>
<td>5 mg/m³</td>
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</tr>
<tr>
<td>Germany - TRGS 900 - TWAs</td>
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</tr>
<tr>
<td>Germany (DFG) - MAK</td>
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<tr>
<td>Switzerland OEL -TWAs</td>
<td>4 mg/m³</td>
<td>0.3 mg/m³</td>
</tr>
</tbody>
</table>

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

Titanium dioxide
ACGIH Threshold Limit Value (TWA) 10 mg/m³
ACGIH OELs - Notice of Intended Changes Listed
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
Estonia OEL - TWA 5 mg/m³
France OEL - TWA 10 mg/m³
Greece OEL - TWA 10 mg/m³
  5 mg/m³
Ireland OEL - TWAs 10 mg/m³
  4 mg/m³
Latvia OEL - TWA 10 mg/m³
Lithuania OEL - TWA 5 mg/m³
OSHA - Final PELs - TWAs: 15 mg/m³
Poland OEL - TWA 10.0 mg/m³
Portugal OEL - TWA 10 mg/m³
Romania OEL - TWA 10 mg/m³
Russia OEL - TWA 10 mg/m³
Spain OEL - TWA 10 mg/m³
Sweden OEL - TWAs 5 mg/m³
Switzerland OEL -TWAs 3 mg/m³
Vietnam OEL - TWAs 6 mg/m³
  5 mg/m³
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

<table>
<thead>
<tr>
<th>Physical State:</th>
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<tbody>
<tr>
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<tr>
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<td>No data available</td>
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<td>Vapor Density (g/ml):</td>
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</tr>
<tr>
<td>Relative Density:</td>
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<td>Viscosity:</td>
<td>No data available</td>
</tr>
</tbody>
</table>

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: 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)

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

Sodium benzoate
- Rat Oral LD50 4,070 mg/kg
- Mouse Oral LD50 1600mg/kg

Xanthan gum
- Rat Oral LD50 > 5000 mg/kg

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

Citric acid
- Rat Oral LD50 3000 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)

Sildenafil citrate
- Eye Irritation Rabbit Moderate
- Skin Irritation Rabbit Non-irritating
- Skin Sensitization Guinea Pig Negative
11. TOXICOLOGICAL INFORMATION

Citric acid
Eye Irritation  Rabbit  Severe
Skin Irritation  Rabbit  Mild

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

Sodium benzoate
10 Day(s)  Rat  Oral  27370 mg/kg  LOAEL  Liver, Blood
10 Day(s)  Mouse  Oral  45 g/kg  LOAEL  Liver, Kidney, Blood, Ureter, Bladder

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))

Sodium benzoate
Embryo / Fetal Development  Rat  Oral  44 g/kg  LOEL  Developmental toxicity

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

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.

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

Colloidal silicon dioxide
IARC:  Group 3 (Not Classifiable)

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. Harmful effects to aquatic organisms could occur.
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:** No data available

**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
15. REGULATORY INFORMATION

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.

<table>
<thead>
<tr>
<th>Material</th>
<th>CERCLA/SARA 313 Emission reporting</th>
<th>California Proposition 65</th>
<th>Inventory - United States TSCA - Sect. 8(b)</th>
<th>Australia (AICS):</th>
<th>EU EINECS/ELINCS List</th>
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<tbody>
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15. REGULATORY INFORMATION

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<td>California Proposition 65</td>
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<td>EU EINECS/ELINCS List</td>
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<td></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
Serious eye damage/eye irritation-Cat.2A; H319 - Causes serious eye irritation

Xn - Harmful
Xi - Irritant

R22 - Harmful if swallowed.
R36 - Irritating to eyes.

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

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 7 - Handling and Storage. Updated Section 11 - Toxicology Information. Updated Section 16 - Other Information. Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 15 - Regulatory Information.

Revision date: 04-Sep-2014

Prepared by: Product Stewardship Hazard Communication

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