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

Product Identifier

Material Name: Donepezil hydrochloride film coated tablets

Trade Name: ARICEPT; ERANZ; Donepezil Pfizer

Chemical Family: Mixture

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

Intended Use: Pharmaceutical product for the treatment of Alzheimer's disease

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: CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification

Acute Oral Toxicity: Category 4

EU Classification:

EU Indication of danger: Harmful

EU Risk Phrases:

R22 - Harmful if swallowed.

Label Elements

Signal Word: Warning
Hazard Statements: H302 - Harmful if swallowed

Precautionary Statements:
P264 - Wash hands thoroughly after handling
P270 - Do not eat, drink or smoke when using this product
P301+ P312 - IF SWALLOWED: Call a POISON CENTRE or doctor/physician if you feel unwell
P330 - Rinse mouth
P501 - Dispose of contents/container in accordance with all local and national regulations
SAFETY DATA SHEET

Material Name: Donepezil hydrochloride film coated tablets
Revision date: 06-Mar-2015

Other Hazards

Note: This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning 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>Donepezil hydrochloride</td>
<td>120011-70-3</td>
<td>Not Listed</td>
<td>T;R25</td>
<td>Acute Tox.3 (H301)</td>
<td>3.7</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>Starch</td>
<td>9005-25-8</td>
<td>232-679-6</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<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>
</tbody>
</table>

<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>Lactose NF, monohydrate</td>
<td>64044-51-5</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Hydroxypropyl cellulose</td>
<td>9004-64-2</td>
<td>Not Listed</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.
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**

- **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:** Formation of toxic gases is possible during heating or fire.
  - **Fire / Explosion Hazards:** Not applicable

- **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. 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**
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

**Donepezil hydrochloride**

- Pfizer OEL TWA-8 Hr: 150µg/m³

**Magnesium stearate**

- ACGIH Threshold Limit Value (TWA): 10 mg/m³
- Lithuania OEL - TWA: 5 mg/m³
- Sweden OEL - TWAs: 5 mg/m³

**Starch**

- ACGIH Threshold Limit Value (TWA): 10 mg/m³
- Australia TWA: 10 mg/m³
- Belgium OEL - TWA: 10 mg/m³
- Bulgaria OEL - TWA: 10.0 mg/m³
- Czech Republic OEL - TWA: 4.0 mg/m³
- Greece OEL - TWA: 10 mg/m³
  - 5 mg/m³
- Ireland OEL - TWAs: 10 mg/m³
  - 4 mg/m³
- OSHA - Final PELS - TWAs: 15 mg/m³
- Portugal OEL - TWA: 10 mg/m³
- Slovakia OEL - TWA: 4 mg/m³
- Spain OEL - TWA: 10 mg/m³
- Switzerland OEL - TWAs: 3 mg/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
  - 4 mg/m³
- Latvia OEL - TWA: 2 mg/m³
- OSHA - Final PELS - TWAs: 15 mg/m³
- Portugal OEL - TWA: 10 mg/m³
- Romania OEL - TWA: 10 mg/m³
- Russia OEL - TWA: 6 mg/m³
- Spain OEL - TWA: 10 mg/m³
- Switzerland OEL - TWAs: 3 mg/m³
- Vietnam OEL - TWAs: 10 mg/m³
  - 5 mg/m³

The exposure limit(s) listed for solid components are only relevant if dust may be generated.

**Analytical Method:**
Analytical method available for Donepezil Hydrochloride. 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).
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

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical State</td>
<td>Tablets</td>
</tr>
<tr>
<td>Odor</td>
<td>No data available</td>
</tr>
<tr>
<td>Molecular Formula</td>
<td>Mixture</td>
</tr>
<tr>
<td>Solvent Solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>Water Solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting/Freezing Point (°C)</td>
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</tr>
<tr>
<td>Boiling Point (°C)</td>
<td>No data available</td>
</tr>
<tr>
<td>Partition Coefficient</td>
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</tr>
<tr>
<td>Hydroxypropyl cellulose</td>
<td>No data available</td>
</tr>
<tr>
<td>Lactose NF, monohydrate</td>
<td>No data available</td>
</tr>
<tr>
<td>Starch</td>
<td>No data available</td>
</tr>
<tr>
<td>Microcrystalline cellulose</td>
<td>No data available</td>
</tr>
<tr>
<td>Donepezil hydrochloride</td>
<td>Predicted 7.4 Log D 4.14</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition Temperature (°C)</td>
<td>No data available</td>
</tr>
<tr>
<td>Evaporation Rate (Gram/s)</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapor Pressure (kPa)</td>
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</tr>
<tr>
<td>Vapor Density (g/ml)</td>
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</tr>
<tr>
<td>Relative Density</td>
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</tr>
<tr>
<td>Viscosity</td>
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<tr>
<td>Flammability:</td>
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</tr>
<tr>
<td>Autoignition Temperature (Solid) (°C):</td>
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<tr>
<td>Flammability (Solids):</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash Point (Liquid) (°C):</td>
<td>No data available</td>
</tr>
<tr>
<td>Upper Explosive Limits (Liquid) (% by Vol.):</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower Explosive Limits (Liquid) (% by Vol.):</td>
<td>No data available</td>
</tr>
</tbody>
</table>

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
10. STABILITY AND REACTIVITY

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.

Known Clinical Effects: Ingestion of this material can cause effects similar to those seen in clinical use including cholinergic crisis, characterized by severe nausea, vomiting, salivation, sweating, slow heart rate, low blood pressure, muscles weakness, respiratory depression, syncope and convulsions.

Acute Toxicity: (Species, Route, End Point, Dose)

<table>
<thead>
<tr>
<th>Microcrystalline cellulose</th>
<th>Rat Oral LD50 &gt; 5000 mg/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat Dermal LD50 &gt; 2000 mg/kg</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Donepezil hydrochloride</th>
<th>Rat Oral LD50 32.6 mg/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mouse Oral LD50 45.2mg/kg</td>
<td></td>
</tr>
<tr>
<td>Rat Intravenous LD50 7.6mg/kg</td>
<td></td>
</tr>
<tr>
<td>Mouse Intravenous LD50 3.7mg/kg</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Magnesium stearate</th>
<th>Rat Oral LD50 &gt; 2000 mg/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat Inhalation LC50 &gt; 2000 mg/m³</td>
<td></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>Microcrystalline cellulose</th>
<th>Skin Irritation Rabbit Non-irritating</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eye Irritation Rabbit Non-irritating</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Donepezil hydrochloride</th>
<th>Eye Irritation Rabbit Irritant</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin Irritation Rabbit Non-irritating</td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Donepezil hydrochloride</th>
<th>13 Week(s) Rat Oral 1 mg/kg/day NOEL None identified</th>
</tr>
</thead>
<tbody>
<tr>
<td>13 Week(s) Dog Oral 1 mg/kg/day NOEL Central Nervous System</td>
<td></td>
</tr>
<tr>
<td>12 Month(s) Rat Oral 3 mg/kg/day NOEL Central Nervous System</td>
<td></td>
</tr>
<tr>
<td>12 Month(s) Dog Oral 5 mg/kg/day NOEL Central Nervous System</td>
<td></td>
</tr>
</tbody>
</table>

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))
11. TOXICOLOGICAL INFORMATION

**Donepezil hydrochloride**

Embryo / Fetal Development  
Rat  Oral  1 mg/kg/day  NOEL  Maternal toxicity, Not teratogenic  
Embryo / Fetal Development  
Rabbit  Oral  3 mg/kg/day  NOEL  Maternal Toxicity, Not Teratogenic

**Genetic Toxicity:** (Study Type, Cell Type/Organism, Result)

**Donepezil hydrochloride**  
Bacterial Mutagenicity (Ames)  
*Salmonella*, *E. coli*  Negative  
*In Vitro* Chromosome Aberration  
Chinese Hamster Ovary (CHO) cells  Positive  
*In Vivo* Micronucleus  
Mouse  Negative

**Carcinogenicity:** (Duration, Species, Route, Dose, End Point, Effect(s))

**Donepezil hydrochloride**

88 Week(s)  Mouse  No route specified  180 mg/kg/day  NOEL  Not carcinogenic  
104 Week(s)  Rat  No route specified  30 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.

12. ECOLOGICAL INFORMATION

**Environmental Overview:**  
Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided.

**Toxicity:**  
No data available

**Persistence and Degradability:**  
No data available

**Bio-accumulative Potential:**  

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

**Donepezil hydrochloride**

Predicted  7.4  Log D  4.14

**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:
Class D, Division 2, Subdivision B

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

Magnesium stearate
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

Lactose NF, 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

Starch
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
15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>EU EINECS/ELINCS List</th>
<th>232-679-6</th>
</tr>
</thead>
</table>

**Hydroxypropyl cellulose**
- 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

**Microcrystalline cellulose**
- 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

16. OTHER INFORMATION

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

Acute toxicity, oral-Cat.3; H301 - Toxic if swallowed
Serious eye damage/eye irritation-Cat.2A; H319 - Causes serious eye irritation

T - Toxic
Xi - Irritant

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

**Data Sources:** Pfizer proprietary drug development information.

**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.

**Revision date:** 06-Mar-2015

**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