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

Material Name: Donepezil Hydrochloride Orally Disintegrating Tablets

Trade Name: ARICEPT ODT
Chemical Family: Mixture
Intended Use: Pharmaceutical product for the treatment of Alzheimer's disease

2. HAZARDS IDENTIFICATION

Appearance: Tablets, White or Yellow
Signal Word: WARNING

Statement of Hazard: Harmful if swallowed.

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.

EU Classification
EU Indication of danger: Harmful

EU Hazard Symbols: Xn

EU Risk Phrases: R22 - Harmful if swallowed.


Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates 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>Donepezil hydrochloride</td>
<td>120011-70-3</td>
<td>Not Listed</td>
<td>T;R25</td>
<td>5 or 10 ***</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Xi;R36</td>
<td></td>
</tr>
<tr>
<td>Colloidal silicon dioxide</td>
<td>7631-86-9</td>
<td>231-545-4</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>Ferric oxide yellow</td>
<td>51274-00-1</td>
<td>257-098-5</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Polyvinyl alcohol</td>
<td>9002-89-5</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Carrageenan</td>
<td>9000-07-1</td>
<td>232-524-2</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

Additional Information:

* Proprietary
*** per tablet/capsule/lozenge/suppository
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: May emit toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, hydrogen chloride and other chlorine-containing compounds.

Fire Fighting Procedures: During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

Fire / Explosion Hazards: 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 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.

Donepezil hydrochloride
  Pfizer OEL TWA-8 Hr: 150µg/m³

Colloidal silicon dioxide
  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
  Ireland OEL - TWAs Listed
  Latvia OEL - TWA Listed
  OSHA - Final PELs - Table Z-3 Mineral D: - (80)%(SiO₂) mg/m³ TWA
  TWA-20 mppcf
  Slovenia OEL - TWA Listed

Ferric oxide yellow
  Bulgaria OEL - TWA Listed
  Czech Republic OEL - TWA Listed


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.
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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: Tablets
Molecular Formula: Mixture
Color: White
Molecular Weight: Mixture

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

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)

Donepezil hydrochloride
Rat Oral LD50 32.6 mg/kg
Mouse Oral LD50 45.2 mg/kg
Rat Intravenous LD50 7.6 mg/kg
Mouse Intravenous LD50 3.7 mg/kg

Mannitol
Rat Oral LD 50 13500 mg/kg
Mouse Oral LD 50 22 g/kg

Irritation / Sensitization: (Study Type, Species, Severity)

Donepezil hydrochloride
Eye Irritation Rabbit Irritant
Skin Irritation Rabbit Non-irritating

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)
11. TOXICOLOGICAL INFORMATION

Donepezil hydrochloride
13 Week(s)  Rat  Oral  1 mg/kg/day  NOEL  None identified
13 Week(s)  Dog  Oral  1 mg/kg/day  NOEL  Central Nervous System
12 Month(s) Rat  Oral  3 mg/kg/day  NOEL  Central Nervous System
12 Month(s) Dog  Oral  5 mg/kg/day  NOEL  Central Nervous System

Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

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
    12 Month(s)  Rat  No route specified  180 mg/kg/day  NOEL  Not carcinogenic
    12 Month(s)  Dog  No route specified  5 mg/kg/day  NOEL  Not carcinogenic
    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.

Carrageenan
    IARC:  Group 2B (Carrageenan, degraded)
            Group 3 (Carrageenan, native)
    OSHA:  Present

Colloidal silicon dioxide
    IARC:  Group 3

Polyvinyl alcohol
    IARC:  Group 3

12. ECOLOGICAL INFORMATION

Environmental Overview:  Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided.
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 Symbol: Xn
EU Indication of danger: Harmful
EU Risk Phrases: R22 - Harmful if swallowed.

EU Safety Phrases: S26 - In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S28 - After contact with skin, wash immediately with plenty of water.
S45 - In case of accident or if you feel unwell seek medical advice immediately (show the label where possible).

OSHA Label:
WARNING
Harmful if swallowed.

Canada - WHMIS: Classifications
WHMIS hazard class:
Class D, Division 1, Subdivision A
Class D, Division 2, Subdivision B

Colloidal silicon dioxide
Inventory - United States TSCA - Sect. 8(b) Listed
15. REGULATORY INFORMATION

| Material Name: Donepezil Hydrochloride Orally Disintegrating Tablets |
| Revision date: 10-Nov-2010 |

| Australia (AICS): | Listed |
| EU EINECS/ELINCS List | 231-545-4 |

Mannitol

| Inventory - United States TSCA - Sect. 8(b): | Listed |
| Australia (AICS): | Listed |
| REACH - Annex IV - Exemptions from the obligations of Register: | Present |
| EU EINECS/ELINCS List | 200-711-8 |

Ferric oxide yellow

| Inventory - United States TSCA - Sect. 8(b): | Listed |
| Australia (AICS): | Listed |
| Standard for the Uniform Scheduling for Drugs and Poisons: | Schedule 2, Schedule 4, Schedule 5, Schedule 6 |
| EU EINECS/ELINCS List | 257-098-5 |

Polyvinyl alcohol

| Inventory - United States TSCA - Sect. 8(b): | Listed |
| Australia (AICS): | Listed |

Carrageenan

| Inventory - United States TSCA - Sect. 8(b): | Listed |
| Australia (AICS): | Listed |
| EU EINECS/ELINCS List | 232-524-2 |

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R25 - Toxic 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 4 - First Aid Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 15 - Regulatory Information.

Prepared by: Product Stewardship Hazard Communications
Pfizer Global Environment, Health, and Safety Operations

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End of Safety Data Sheet