1. PRODUCT AND COMPANY IDENTIFICATION

Product Name: Ascendin Tablets
Common Name: Not available
Chemical Name: Not applicable
Synonyms: Adisen, Amoxan, Asendin, Demolox
Product Use: Pharmaceutical product
Classification: Antidepressant
Supplier: Wyeth
P.O. Box 8299
Philadelphia, PA 19101 USA.
Telephone: 1-610-688-4400

Emergency Telephone Number
Chemtrec USA, Puerto Rico, Canada 1-800-424-9300
Chemtrec International 1-703-527-3887

2. HAZARDS IDENTIFICATION

Emergency Overview
This contains an active pharmaceutical ingredient that can affect body functions; handle with caution.

Appearance: Pharmaceutical tablet
Physical State: Solid
Odor: Not available

Potential Physical Hazards
Powders and solids are presumed to be combustible.

Potential Health Effects

<table>
<thead>
<tr>
<th>Eyes</th>
<th>Not available</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin</td>
<td>Not available</td>
</tr>
<tr>
<td>Inhalation</td>
<td>Not available</td>
</tr>
<tr>
<td>Ingestion</td>
<td>The most common effects may include confusion, convulsions, disturbed concentration, severe drowsiness, enlarged pupils, fast, slow, or irregular heartbeat, fever, hallucinations, restlessness and agitation, shortness of breath or troubled breathing, severe unusual tiredness or weakness, vomiting, repetitive involuntary movements, and neuroleptic malignant syndrome. May cause harm to the unborn child.</td>
</tr>
</tbody>
</table>

Please see Patient Package Insert for further information.

Therapeutic Target Organ(s)
Central nervous system.

Potential Environmental Effects
There is no known ecological information for this product.
3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Common Name</th>
<th>CAS-No</th>
<th>Composition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amoxapine</td>
<td>14028-44-5</td>
<td>25-150 mg/tablet</td>
</tr>
<tr>
<td>Inactive Ingredients</td>
<td>Not applicable</td>
<td>Remainder</td>
</tr>
</tbody>
</table>

4. FIRST AID MEASURES

**Eye Contact**
In the case of contact with eyes, rinse immediately with plenty of water for 15 minutes and seek medical advice.

**Skin Contact**
Take off contaminated clothing and shoes immediately. Wash off immediately with soap and plenty of water. If skin irritation persists, call a physician.

**Inhalation**
Move to fresh air. Artificial respiration and/or oxygen may be necessary. If symptoms persist, call a physician.

**Ingestion**
If symptoms persist, call a physician. Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person.

5. FIRE-FIGHTING MEASURES

**Flammable Properties**
Presumed to be a combustible particulate solid.

**Extinguishing Media**

- **Suitable Extinguishing Media**
  Use water spray, foam, dry chemical or carbon dioxide.

- **Unsuitable Extinguishing Media**
  Do NOT use water jet.

**Fire Fighting**
Evacuate area and fight fire from a safe distance. Cool closed containers exposed to fire with water spray. In the event of fire and/or explosion do not breathe fumes.

**Hazardous Combustion Products**
Carbon oxides, nitrogen oxides.

**Protective Equipment and Precautions for Firefighters**
In the event of fire, wear self-contained breathing apparatus and special protective equipment for fire fighters.

6. ACCIDENTAL RELEASE MEASURES

**Personal Precautions**
Refer to protective measures listed in Sections 7 and 8.

**Environmental Precautions**
Prevent product from entering drains. Local authorities should be advised if a significant spill cannot be contained.

**Methods for Containment**
Not available

**Methods for Cleaning up**
Take up mechanically and collect in suitable container for disposal. Clean contaminated surface thoroughly. Avoid formation of dust and aerosols.
7. HANDLING AND STORAGE

Handling
For personal protection see Section 8. Handle in accordance with good industrial hygiene and safety practice. Skin should be washed after contact. Avoid formation of dust and aerosols.

Storage
No special safety precautions required. Keep container tightly closed.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Common Name  Exposure Guideline
Amoxapine  250 mcg/m³

Engineering Controls
Apply technical measures to comply with the occupational exposure guideline. Local exhaust ventilation is needed for limited open handling or where aerosols may be generated.

Personal Protective Equipment

<table>
<thead>
<tr>
<th>Eye/face Protection</th>
<th>Engineering Controls</th>
<th>Provide eye protection based on risk assessment.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin Protection</td>
<td></td>
<td>Wear nitrile or latex gloves. Wear protective garment.</td>
</tr>
<tr>
<td>Respiratory Protection</td>
<td></td>
<td>Base respirator selection on a risk assessment.</td>
</tr>
</tbody>
</table>

General Hygiene
When using, do not eat, drink or smoke. General industrial hygiene practice. Wash hands before breaks and at the end of workday.

Other
Limit access to only personnel trained in the safe handling of this material. Consult a health and safety professional for specific PPE, respirator, and risk assessment guidance.

9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>Pharmaceutical tablet</td>
<td>Physical State</td>
<td>Solid</td>
</tr>
<tr>
<td>Color</td>
<td>Various</td>
<td>Odor</td>
<td>Not available</td>
</tr>
<tr>
<td>Odor Threshold</td>
<td>Not available</td>
<td></td>
<td></td>
</tr>
<tr>
<td>pH</td>
<td>Not available</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Specific Gravity</td>
<td>Not applicable</td>
<td>Water Solubility</td>
<td>Insoluble in water</td>
</tr>
<tr>
<td>Solubility</td>
<td>Not applicable</td>
<td>Evaporation Rate</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Partition Coefficient (n-octanol/water)</td>
<td>Not available</td>
<td>Vapor Density</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Vapor Pressure</td>
<td>Not applicable</td>
<td>Autoignition Temperature</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Boiling Point</td>
<td>Not applicable</td>
<td>Method</td>
<td>None</td>
</tr>
<tr>
<td>Flash Point</td>
<td>Not applicable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Melting Point</td>
<td>Not applicable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Flammability Limits in Air</td>
<td>Upper Not applicable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Explosion Limits</td>
<td>Upper Not applicable</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Lower Not applicable</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
10. STABILITY AND REACTIVITY

Chemical Stability  Stable at room temperature.

Conditions to Avoid  No data available

Materials to Avoid  No materials to be especially mentioned.

Hazardous Decomposition Products  None under normal use.

Possibility of Hazardous Reactions  None under normal use.

11. TOXICOLOGICAL INFORMATION

The following effects are based on the Active Pharmaceutical Ingredient.

Acute Toxicity

Amoxapine

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>LD50 Oral</td>
<td>313 - 780 mg/kg rats</td>
</tr>
<tr>
<td></td>
<td>105 - 185 mg/kg mice</td>
</tr>
<tr>
<td>Acute Dermal Irritation</td>
<td>Not available</td>
</tr>
<tr>
<td>Primary Eye Irritation</td>
<td>Not available</td>
</tr>
<tr>
<td>Sensitization</td>
<td>No data available</td>
</tr>
</tbody>
</table>

Multiple Dose Toxicity

Amoxapine

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>No Toxicologic Effect</td>
<td>Decreased body weight and food consumption was observed in the subacute toxicity studies in rats. In dogs, signs of CNS activity characterized by tremors, akinesia, transient mammary gland enlargement (female, 6-month study) and convulsions were observed in the multi-dose toxicity studies.</td>
</tr>
</tbody>
</table>

Maximum Tolerated Dose (MTD), Oral

Amoxapine

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carcinogenicity</td>
<td>Long-term toxicity studies in rats revealed an evidence of slightly increased incidence of pancreatic islet cell hyperplasia. There was no evidence of mammary neoplasia that could be attributed to drug administration.</td>
</tr>
<tr>
<td>Genetic Toxicity</td>
<td>No evidence of mutagenicity was observed in a battery of <em>in vitro</em> and <em>in vivo</em> assays.</td>
</tr>
<tr>
<td>Reproductive Toxicity</td>
<td>Embryotoxic effects and fetotoxic effects such as intrauterine death, stillbirth, and decreased birth weight, and decreased postnatal survival were observed in animal studies at doses approximating human dose or many times the human dose.</td>
</tr>
<tr>
<td>Developmental Toxicity</td>
<td>No evidence of teratogenic effects was observed in mice, rats, and rabbits.</td>
</tr>
</tbody>
</table>

Amoxapine

<table>
<thead>
<tr>
<th>Parameter</th>
<th>No data available</th>
</tr>
</thead>
</table>
12. ECOLOGICAL INFORMATION

The following effects are based on the Active Pharmaceutical Ingredient.

Chemical Fate Information Not available
Ecotoxicity Not available

13. DISPOSAL CONSIDERATIONS

Waste Disposal Method Dispose of in accordance with local and national regulations.

14. TRANSPORT INFORMATION

Transport Information This material is not classified as hazardous for transport.

U.S. Department of Transport (DOT) Not regulated
Canadian Transport of Dangerous Goods (TDG) Not regulated
International Civil Aviation Organization (ICAO) Not regulated
International Air Transport Association (IATA) Not regulated
International Maritime Dangerous Goods (IMDG)/International Maritime Organization (IMO) Not regulated
Transport of Dangerous Goods by Rail (RID) Not regulated
Transport of Dangerous Goods by Road (ADR) Not regulated
Transportation of Dangerous Goods via Inland Waterways (ADN) Not regulated

15. REGULATORY INFORMATION

USA

Federal Regulations

OSHA Regulatory Status
This material is not considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200)

SARA 313
Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40n of the Code of Federal Regulations, Part 372.

SARA 311/312 Hazardous Categorization

<table>
<thead>
<tr>
<th>Hazard Category</th>
<th>Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute Health Hazard</td>
<td>Yes</td>
</tr>
<tr>
<td>Chronic Health Hazard</td>
<td>No</td>
</tr>
<tr>
<td>Sudden Release of Pressure Hazard</td>
<td>No</td>
</tr>
<tr>
<td>Reactive Hazard</td>
<td>No</td>
</tr>
</tbody>
</table>
This product does not contain any HAPs.

**State Regulations**

**California Proposition 65**
Listed on Proposition 65 as Developmental.

**Canada**
Not classified

**WHMIS Hazard Class**
Non-controlled

**European Union**
In accordance with EC directives or respective national laws, the product does not need to be classified nor labeled.

### 16. OTHER INFORMATION

**Prepared By**
Wyeth Department of Environment, Health & Safety

**Format**
This MSDS was prepared in accordance with ANSI Z400.1-2004.

**List of References**
See Patient Package Insert for more information.

**Revision Summary**
Administrative

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End of MSDS