1. PRODUCT AND COMPANY IDENTIFICATION

Product Name Isordil
Common Name Not available
Chemical Name Not applicable
Synonyms Isordil Tablets, Isordil Titradose, Isordil Tembids, Isosorbide dinitrate
Product Use Pharmaceutical product
Classification Vasodilating Agent
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.

<table>
<thead>
<tr>
<th>Appearance</th>
<th>Physical State</th>
<th>Odor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmaceutical tablet or capsule</td>
<td>Solid</td>
<td>Not available</td>
</tr>
</tbody>
</table>

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>See Ingestion</td>
</tr>
<tr>
<td>Inhalation</td>
<td>See Ingestion and/or Other</td>
</tr>
<tr>
<td>Ingestion</td>
<td>The most common effects may include dilation of blood vessels, lowered blood pressure, headache, lightheadedness and dizziness.</td>
</tr>
</tbody>
</table>

Please see Patient Package Insert for further information.

Therapeutic Target Organ(s) Cardiovascular system

Not listed by OSHA, NTP or IARC.

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>Isosorbide dinitrate</td>
<td>87-33-2</td>
<td>2.5 - 40 mg/tablet or capsule</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
Isosorbide dinitrate

### Exposure Guideline
20 mcg/m³ (skin absorbed)

### 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>Protection</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eye/face Protection</td>
<td>Provide eye protection based on risk assessment.</td>
</tr>
<tr>
<td>Skin Protection</td>
<td>Wear nitrile or latex gloves. Wear protective garment.</td>
</tr>
<tr>
<td>Respiratory Protection</td>
<td>Base respirator selection on a risk assessment.</td>
</tr>
<tr>
<td>General Hygiene Considerations</td>
<td>When using, do not eat, drink or smoke. General industrial hygiene practice. Wash hands before breaks and at the end of workday.</td>
</tr>
<tr>
<td>Other</td>
<td>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.</td>
</tr>
</tbody>
</table>

## 9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Appearance</strong></td>
<td>Pharmaceutical tablet or capsule</td>
</tr>
<tr>
<td><strong>Color</strong></td>
<td>Various</td>
</tr>
<tr>
<td><strong>Odor Threshold</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>Molecular Formula</strong></td>
<td>Not applicable</td>
</tr>
<tr>
<td><strong>pH</strong></td>
<td>Not applicable</td>
</tr>
<tr>
<td><strong>Specific Gravity</strong></td>
<td>Not applicable</td>
</tr>
<tr>
<td><strong>Solubility</strong></td>
<td>Not applicable</td>
</tr>
<tr>
<td><strong>Partition Coefficient</strong></td>
<td>Not applicable</td>
</tr>
<tr>
<td><strong>(n-octanol/water)</strong></td>
<td>Not applicable</td>
</tr>
<tr>
<td><strong>Boiling Point</strong></td>
<td>Not applicable</td>
</tr>
<tr>
<td><strong>Flash Point</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>Melting Point</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>Flammability Limits</strong></td>
<td>Not applicable</td>
</tr>
<tr>
<td><strong>Explosion Limits</strong></td>
<td>Not applicable</td>
</tr>
<tr>
<td><strong>Autoignition Temperature</strong></td>
<td>Not applicable</td>
</tr>
<tr>
<td><strong>Method</strong></td>
<td>None</td>
</tr>
<tr>
<td><strong>Upper</strong></td>
<td>Not applicable</td>
</tr>
<tr>
<td><strong>Lower</strong></td>
<td>Not applicable</td>
</tr>
</tbody>
</table>

**Physical State**
Solid

**Odor**
Not available

**Molecular Weight**
Not applicable

**Water Solubility**
Not available

**Evaporation Rate**
Not applicable

**Vapor Pressure**
Not applicable
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
Isosorbide dinitrate
- LD50 Oral ~ 1100 mg/kg, rats
- Acute Dermal Irritation No data available
- Primary Eye Irritation No data available
- Sensitization No data available

Multiple Dose Toxicity
Isosorbide dinitrate
- No Toxicologic Effect No data available

Maximum Tolerated Dose (MTD), Oral
Isosorbide dinitrate
- Carcinogenicity No evidence of carcinogenicity was observed in rats.
- Genetic Toxicity No evidence of mutagenicity was observed in a battery of in vitro and in vivo assays.
- Reproductive Toxicity Studies in rats were found to have no effect on fertility.
- Developmental Toxicity Studies in rats given at oral doses of 35 and 150 times the maximum daily-recommended human dose have shown a dose-related increase in embryotoxicity.

Isosorbide dinitrate
- Target Organ(s) of Toxicity No data available

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
- Acute Health Hazard No
- Chronic Health Hazard No
- Fire Hazard No
- Sudden Release of Pressure Hazard No
- Reactive Hazard No

This product does not contain any HAPs.

State Regulations

California Proposition 65
This product does not contain any Proposition 65 chemicals.

Canada
Not classified
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: Not applicable

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End of MSDS