1. PRODUCT AND COMPANY IDENTIFICATION

Product Name: Lodine Solid Products
Common Name: Not available
Chemical Name: Not applicable
Synonyms: Lodine, Lodine XL, Etodolac Tablets, Etodolac Capsules, Etodolac Extended Release Tablets
Product Use: Pharmaceutical product
Classification: Nonsteroidal Anti-inflammatory 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.

Appearance: Pharmaceutical Tablet or Capsule
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 hypertension, myocardial infarction, stroke, congestive heart failure, edema, gastrointestinal effects (ulcer, bleeding, perforation), renal disease, anaphylactoid reactions, skin reactions, hepatic effects, and anemia. May cause harm to the unborn child. May cause harm to breastfed babies. Please see Patient Package Insert for further information.</td>
</tr>
<tr>
<td>Therapeutic Target Organ(s)</td>
<td>Systemic</td>
</tr>
<tr>
<td>Potential Environmental Effects</td>
<td>There is no known ecological information for this product.</td>
</tr>
</tbody>
</table>
3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Common Name</th>
<th>CAS-No</th>
<th>Composition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Etodolac</td>
<td>41340-25-4</td>
<td>200-600 mg/tablet or capsule</td>
</tr>
<tr>
<td>Inactive Ingredients</td>
<td>Not applicable</td>
<td>.? mg/tablet</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

Engineering Controls
No special precautions required.

Personal Protective Equipment

<table>
<thead>
<tr>
<th>Eye/face Protection</th>
<th>Skin Protection</th>
<th>Respiratory Protection</th>
</tr>
</thead>
</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>Appearance</th>
<th>Physical State</th>
<th>Solubility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmaceutical Tablet or Capsule</td>
<td>Physical State</td>
<td>Solid</td>
</tr>
<tr>
<td>Color</td>
<td>Odor</td>
<td>Not available</td>
</tr>
<tr>
<td>Various</td>
<td>Odor</td>
<td>Not available</td>
</tr>
<tr>
<td>Odor Threshold</td>
<td>Odor</td>
<td>Not available</td>
</tr>
<tr>
<td>pH</td>
<td>Odor</td>
<td>Not available</td>
</tr>
<tr>
<td>Not applicable</td>
<td>Odor</td>
<td>Not available</td>
</tr>
<tr>
<td>Specific Gravity</td>
<td>Water Solubility</td>
<td>Insoluble</td>
</tr>
<tr>
<td>Not applicable</td>
<td>Water Solubility</td>
<td>Insoluble</td>
</tr>
<tr>
<td>Solubility</td>
<td>Evaporation Rate</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Not applicable</td>
<td>Evaporation Rate</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Partition Coefficient</td>
<td>Vapor Pressure</td>
<td>Not applicable</td>
</tr>
<tr>
<td>(n-octanol/water)</td>
<td>Vapor Pressure</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Boiling Point</td>
<td>Autoignition Temperature</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Not applicable</td>
<td>Autoignition Temperature</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Flash Point</td>
<td>Method</td>
<td>None</td>
</tr>
<tr>
<td>Not available</td>
<td>Method</td>
<td>None</td>
</tr>
<tr>
<td>Melting Point</td>
<td>Lower</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Not available</td>
<td>Lower</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Flammability Limits in Air</td>
<td>Lower</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Upper</td>
<td>Lower</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Explosion Limits</td>
<td>Lower</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Upper</td>
<td>Lower</td>
<td>Not applicable</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

<table>
<thead>
<tr>
<th>Compound</th>
<th>LD50 Oral</th>
<th>Dermal Irritation</th>
<th>Eye Irritation</th>
<th>Sensitization</th>
</tr>
</thead>
<tbody>
<tr>
<td>Etodolac</td>
<td>883 mg/kg mice</td>
<td>Not applicable</td>
<td>Not applicable</td>
<td>Not applicable</td>
</tr>
<tr>
<td></td>
<td>132 mg/kg rats</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>2250 mg/kg rabbits</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Multiple Dose Toxicity

Etodolac

No Toxicologic Effect
See Carcinogenicity

Maximum Tolerated Dose (MTD), Oral

Etodolac

Carcinogenicity
Chronic oral toxicity studies in mice and rats revealed no evidence of carcinogenic potential.

Genetic Toxicity
Not mutagenic in AMES Test. Non-mutagenic in mouse lymphoma cells assay. Non-mutagenic in the mouse micronucleus assay. An increase in the number of gaps among the treated cultures was observed in the in vitro human peripheral lymphocyte test.

Reproductive Toxicity
Reproduction studies in rats revealed an evidence of reduced implantation, but no impairment of fertility.

Developmental Toxicity
In teratology studies, isolated occurrences of alterations in limb development were found in rats and rabbits. However, the frequency and dosage group distribution in initial and repeated studies did not establish a clear drug or dose response relationship.

Etodolac

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  Yes
Fire Hazard  No
Sudden Release of Pressure Hazard  No
Reactive Hazard  No
This product does not contain any HAPs.

**State Regulations**

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

**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.

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**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