



**Lodine Solid Products**

**Preparation Date** 20-Nov-2006

**Revision Date** Not applicable

**Revision Number** Not applicable

**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**

**Eyes** Not available  
**Skin** Not available  
**Inhalation** Not available  
**Ingestion** 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.

**Therapeutic Target Organ(s)** Systemic.

Not listed by OSHA, NTP or IARC.

**Potential Environmental Effects** There is no known ecological information for this product.

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Common Name	CAS-No	Composition
Etodolac	41340-25-4	200-600 mg/tablet or capsule
Inactive Ingredients	Not applicable	.? mg/tablet

### 4. FIRST AID MEASURES

<b>Eye Contact</b>	In the case of contact with eyes, rinse immediately with plenty of water for 15 minutes and seek medical advice.
<b>Skin Contact</b>	Take off contaminated clothing and shoes immediately. Wash off immediately with soap and plenty of water. If skin irritation persists, call a physician.
<b>Inhalation</b>	Move to fresh air. Artificial respiration and/or oxygen may be necessary. If symptoms persist, call a physician.
<b>Ingestion</b>	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

<b>Flammable Properties</b>	Presumed to be a combustible particulate solid.
<b>Extinguishing Media</b>	
<b>Suitable Extinguishing Media</b>	Use water spray, foam, dry chemical or carbon dioxide.
<b>Unsuitable Extinguishing Media</b>	Do NOT use water jet.
<b>Fire Fighting</b>	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.
<b>Hazardous Combustion Products</b>	Carbon oxides, nitrogen oxides.
<b>Protective Equipment and Precautions for Firefighters</b>	In the event of fire, wear self-contained breathing apparatus and special protective equipment for fire fighters.

### 6. ACCIDENTAL RELEASE MEASURES

<b>Personal Precautions</b>	Refer to protective measures listed in Sections 7 and 8.
<b>Environmental Precautions</b>	Prevent product from entering drains. Local authorities should be advised if a significant spill cannot be contained.
<b>Methods for Containment</b>	Not available
<b>Methods for Cleaning up</b>	Take up mechanically and collect in suitable container for disposal. Clean contaminated surface thoroughly. Avoid formation of dust and aerosols.

## 7. HANDLING AND STORAGE

<b>Handling</b>	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.
<b>Storage</b>	No special safety precautions required. Keep container tightly closed.

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<b>Engineering Controls</b>	No special precautions required.
<b>Personal Protective Equipment</b>	
<b>Eye/face Protection</b>	Provide eye protection based on risk assessment.
<b>Skin Protection</b>	Wear nitrile or latex gloves. Wear protective garment.
<b>Respiratory Protection</b>	Base respirator selection on a risk assessment.
<b>General Hygiene Considerations</b>	When using, do not eat, drink or smoke. General industrial hygiene practice. Wash hands before breaks and at the end of workday.
<b>Other</b>	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

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

## 10. STABILITY AND REACTIVITY

<b>Chemical Stability</b>	Stable at room temperature.
<b>Conditions to Avoid</b>	No data available
<b>Materials to Avoid</b>	No materials to be especially mentioned.
<b>Hazardous Decomposition Products</b>	None under normal use.
<b>Possibility of Hazardous Reactions</b>	None under normal use.

## 11. TOXICOLOGICAL INFORMATION

The following effects are based on the Active Pharmaceutical Ingredient.

### Acute Toxicity

<b>Etodolac</b>	
<b>LD50 Oral</b>	883 mg/kg mice 132 mg/kg rats 2250 mg/kg rabbits
<b>Acute Dermal Irritation</b>	Not applicable
<b>Primary Eye Irritation</b>	Not applicable
<b>Sensitization</b>	Not applicable

### Multiple Dose Toxicity

<b>Etodolac</b>	
<b>No Toxicologic Effect     Dose/Species/Study Length:</b>	See Carcinogenicity

### Maximum Tolerated Dose (MTD), Oral

<b>Etodolac</b>	
<b>Carcinogenicity</b>	Chronic oral toxicity studies in mice and rats revealed no evidence of carcinogenic potential.
<b>Genetic Toxicity</b>	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 <i>in vitro</i> human peripheral lymphocyte test.
<b>Reproductive Toxicity</b>	Reproduction studies in rats revealed an evidence of reduced implantation, but no impairment of fertility.
<b>Developmental Toxicity</b>	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.

<b>Etodolac</b>	
<b>Target Organ(s) of Toxicity</b>	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.

**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

Disclaimer:

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**End of MSDS**