



**Oruvail Products**

Preparation Date 20-Nov-2006

Revision Date 31-Mar-2008

Revision Number 1

**1. PRODUCT AND COMPANY IDENTIFICATION**

**Product Name** Oruvail Products  
**Common Name** Not available  
**Chemical Name** Not applicable  
**Synonyms** Oruvail Extended Release Capsules, Orudis Tablets, Ketoprofen  
**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, anemia, and prolonged bleeding time.

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
Ketoprofen	22071-15-4	25-200 mg/tablet or capsule
Inactive Ingredients	Not applicable	Remainder

### 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>Common Name</b> Ketoprofen	<b>Exposure Guideline</b> 75 mcg/m <sup>3</sup>
<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 in water
<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</b>	Not applicable
<b>Flash Point</b>	Not available	<b>Method</b>	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>Ketoprofen</b>	
<b>LD50 Oral</b>	360 mg/kg mice 62.4 mg/kg rats 1300 mg/kg guinea pigs >1000 mg/kg dogs
<b>Acute Dermal Irritation</b>	Not applicable
<b>Primary Eye Irritation</b>	Not applicable
<b>Sensitization</b>	Not applicable

### Multiple Dose Toxicity

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

### Maximum Tolerated Dose (MTD), Oral

<b>Ketoprofen</b>	
<b>Carcinogenicity</b>	Chronic oral toxicity studies in mice and rats did not reveal any evidence of statistically significant increases in tumor type.
<b>Genetic Toxicity</b>	AMES Test :Negative- Nonmutagenic Negative in sister chromatic exchanges assay.
<b>Reproductive Toxicity</b>	Studies in rats were found to have no effect on fertility and reproductive performance.
<b>Developmental Toxicity</b>	No teratogenic effects were observed in mice and rats. At maternally toxic doses in rabbits, it was embryo/fetotoxic but not teratogenic.

<b>Ketoprofen</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**

This product does not contain any Proposition 65 chemicals.

#### **Canada**

Not classified

#### **WHMIS Hazard Class**

D2B Toxic materials

#### **European Union**

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

## 16. OTHER INFORMATION

<b>Prepared By</b>	Wyeth Department of Environment, Health & Safety
<b>Format</b>	This MSDS was prepared in accordance with ANSI Z400.1-2004.
<b>List of References</b>	Product Profiles
<b>Revision Summary</b>	Changes to Section 8

#### Disclaimer:

The information, data, recommendations, and suggestions appearing in this material safety data sheet (MSDS) and/or in materials regarding our active pharmaceutical ingredients (APIs) or products are based upon tests and data believed to be reliable as of the date of publication. NO REPRESENTATIONS OR WARRANTIES, EITHER EXPRESSED OR IMPLIED, INCLUDING WITHOUT LIMITATION ANY WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, OR ANY OTHER WARRANTY IS MADE WITH REGARD TO THE INFORMATION PROVIDED IN THE MSDS, REGARDING THE API, OR THE PRODUCT TO WHICH THE INFORMATION PERTAINS. Accordingly, Wyeth will not be responsible for any damages resulting from use of, or reliance upon, this information as conditions of use are beyond our control. Users are responsible for assuring the safety of their workers and safe operating conditions, and for determining whether the API or product is suitable for their particular purposes. Users shall assume all risks of their use, handling, and disposal of the API and/or product in accordance with all appropriate and applicable regulations. This information relates only to the API or product designated herein, and does not relate to its use in combination with any other API, material, product, or process. No permission is granted for the use of any API or product in a manner that might infringe on existing patents.

**End of MSDS**