# 1. PRODUCT AND COMPANY IDENTIFICATION

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Oruvail Products</th>
</tr>
</thead>
<tbody>
<tr>
<td>Common Name</td>
<td>Not available</td>
</tr>
<tr>
<td>Chemical Name</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Synonyms</td>
<td>Oruvail Extended Release Capsules, Orudis Tablets, Ketoprofen</td>
</tr>
<tr>
<td>Product Use</td>
<td>Pharmaceutical product</td>
</tr>
<tr>
<td>Classification</td>
<td>Nonsteroidal Anti-inflammatory Agent</td>
</tr>
<tr>
<td>Supplier</td>
<td>Wyeth</td>
</tr>
<tr>
<td></td>
<td>P.O. Box 8299</td>
</tr>
<tr>
<td></td>
<td>Philadelphia, PA 19101 USA.</td>
</tr>
<tr>
<td></td>
<td>Telephone: 1-610-688-4400</td>
</tr>
</tbody>
</table>

**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>Pharmaceutical Tablet or Capsule</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical State</td>
<td>Solid</td>
</tr>
<tr>
<td>Odor</td>
<td>Not available</td>
</tr>
</tbody>
</table>

**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.

**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>Ketoprofen</td>
<td>22071-15-4</td>
<td>25-200 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**

<table>
<thead>
<tr>
<th>Suitable Extinguishing Media</th>
<th>Unsuitable Extinguishing Media</th>
</tr>
</thead>
<tbody>
<tr>
<td>Use water spray, foam, dry chemical or carbon dioxide.</td>
<td>Do NOT use water jet.</td>
</tr>
</tbody>
</table>

**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
Ketoprofen 75 mcg/m³

Engineering Controls
No special precautions required.

Personal Protective Equipment
Eye/face Protection
Provide eye protection based on risk assessment.

Skin Protection
Wear nitrile or latex gloves. Wear protective garment.

Respiratory Protection
Base respirator selection on a risk assessment.

General Hygiene Considerations
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

Appearance
Pharmaceutical Tablet or Capsule

Color
Various

Odor Threshold
Not available

pH
Not applicable

Specific Gravity
Not applicable

Solubility
Not applicable

Partition Coefficient (n-octanol/water)
Not available

Boiling Point
Not applicable

Flash Point
Not available

Melting Point
Not available

Flammability Limits in Air
Upper Not applicable

Explosion Limits
Upper Not applicable

Physical State
Solid

Odor
Not available

Water Solubility
Insoluble in water

Evaporation Rate
Not applicable

Vapor Pressure
Not applicable

Autoignition Temperature Method
Not applicable

Autoignition Temperature Method
None

Lower
Not applicable

Lower
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

Ketoprofen

LD50 Oral
360 mg/kg mice
62.4 mg/kg rats
1300 mg/kg guinea pigs
>1000 mg/kg dogs

Acute Dermal Irritation
Not applicable

Primary Eye Irritation
Not applicable

Sensitization
Not applicable

Multiple Dose Toxicity

Ketoprofen

No Toxicologic Effect
See Carcinogenicity

Dose/Species/Study Length:
See Carcinogenicity

Maximum Tolerated Dose (MTD), Oral

Ketoprofen

Carcinogenicity
Chronic oral toxicity studies in mice and rats did not reveal any evidence of statistically significant increases in tumor type.

Genetic Toxicity
AMES Test : Negative- Nonmutagenic Negative in sister chromatid exchanges assay.

Reproductive Toxicity
Studies in rats were found to have no effect on fertility and reproductive performance.

Developmental Toxicity
No teratogenic effects were observed in mice and rats. At maternally toxic doses in rabbits, it was embryo/fetotoxic but not teratogenic.

Ketoprofen

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
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

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

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End of MSDS