MATERIAL SAFETY DATA SHEET

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

Pfizer Inc
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Emergency telephone number: CHEMTREC (24 hours): 1-800-424-9300
Emergency telephone number: ChemSafe (24 hours): +44 (0)208 762 8322

Material Name: Piroxicam Suppositories
Trade Name: FELDENE(R)
Chemical Family: Mixture
Intended Use: Pharmaceutical product used as non-steroidal, anti-inflammatory drug (nsaid)

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS List</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Piroxicam</td>
<td>36322-90-4</td>
<td>252-974-3</td>
<td>1.05</td>
</tr>
<tr>
<td>Propyl gallate</td>
<td>121-79-9</td>
<td>204-498-2</td>
<td>*</td>
</tr>
</tbody>
</table>

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<thead>
<tr>
<th>Ingredient</th>
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<th>EU EINECS List</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Microcrystalline wax</td>
<td>63231-60-7</td>
<td>264-038-1</td>
<td>*</td>
</tr>
<tr>
<td>Hard fat</td>
<td>Not assigned</td>
<td>Not listed</td>
<td>*</td>
</tr>
</tbody>
</table>

Additional Information: * Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

3. HAZARDS IDENTIFICATION

Appearance: Off-white Suppository
Signal Word: WARNING

Statement of Hazard:
May be harmful if swallowed.
May damage the unborn child.
May cause allergic reaction in aspirin-sensitive individuals
Can cause gastrointestinal and kidney effects
May cause blood, liver, and central nervous system effects

Additional Hazard Information: Short Term:
Not an eye irritant Not a skin irritant (based on animal data) Accidental ingestion may cause effects similar to those seen in clinical use. Individuals sensitive to this chemical or other materials in its chemical class may develop allergic reactions.

Known Clinical Effects:
Ingestion of this material may cause effects similar to those seen in clinical use including serious gastrointestinal toxicity such as bleeding, ulceration, and perforation and kidney toxicity. Clinical use of this drug has caused headache, dizziness, blurred vision, ringing of the ears, skin rash, itching, swelling, liver effects.
EU Indication of danger: Toxic to reproduction: Category 1
Harmful

EU Hazard Symbols:

EU Risk Phrases:
R48/22 - Harmful: danger of serious damage to health by prolonged exposure if swallowed.
R61 - May cause harm to the unborn child.

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

4. FIRST AID MEASURES

Eye Contact: Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.

Skin Contact: Wash skin with soap and water. Remove contaminated clothing and shoes. This material may not be completely removed by conventional laundering. Consult professional laundry service. Do not home launder. If irritation occurs or persists, get medical attention.

Ingestion: Get medical attention immediately. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.

Inhalation: Remove to fresh air. If not breathing, give artificial respiration. Get medical attention immediately.

5. FIRE FIGHTING MEASURES

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

Hazardous Combustion Products: Emits toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, sulfur oxides and other sulfur-containing compounds.

Fire Fighting Procedures: During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

Fire / Explosion Hazards: Not determined

6. ACCIDENTAL RELEASE MEASURES

Health and Safety Precautions: Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

Measures for Environmental Protections: Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
**7. HANDLING AND STORAGE**

**General Handling:** Use appropriate ventilation. Avoid contact with eyes, skin and clothing.

**Storage Conditions:** Store as directed by product packaging.

**8. EXPOSURE CONTROLS / PERSONAL PROTECTION**

Piroxicam

Pfizer OEL TWA-8 Hr: 0.1 mg/m³

The exposure limit(s) listed for solid components are only relevant if dust may be generated.

**Analytical Method:** Analytical method available for Piroxicam. Contact Pfizer Inc for further information.

**Engineering Controls:** Engineering controls should be used as the primary means to control exposures. Good general ventilation should be sufficient to control airborne levels. For laboratory use, handle in a lab fume hood.

**Personal Protective Equipment:**

- **Hands:** Rubber gloves
- **Eyes:** Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is possible.
- **Skin:** Not required for the normal use of this product. Wear protective clothing when working with large quantities.
- **Respiratory protection:** Not required for the normal use of this product. If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

**9. PHYSICAL AND CHEMICAL PROPERTIES:**

**Physical State:** Suppository  
**Color:** Off-white  
**Molecular Formula:** Mixture  
**Molecular Weight:** Mixture

**10. STABILITY AND REACTIVITY**

**Stability:** Stable  
**Conditions to Avoid:** Not determined  
**Incompatible Materials:** As a precautionary measure, keep away from strong oxidizers.  
**Polymerization:** Will not occur

**11. TOXICOLOGICAL INFORMATION**

**General Information:** The information included in this section describes the potential hazards of the active ingredient

**Acute Toxicity: (Species, Route, End Point, Dose)**
Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Irritation / Sensitization: (Study Type, Species, Severity)

Piroxicam
Eye Irritation Rabbit Non-irritating
Skin Irritation Rabbit Non-irritating

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Piroxicam
3 Month(s) Rat Oral 5 mg/kg/day NOAEL Gastrointestinal System
3 Month(s) Monkey Oral 2.5 mg/kg/day Gastrointestinal system
18 Month(s) Rat Oral 1 mg/kg/day NOAEL Gastrointestinal system, Kidney

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Piroxicam
Reproductive & Fertility Rat Oral 10 mg/kg/day NOAEL No effects at maximum dose
Peri-/Postnatal Development Rat Oral 2 mg/kg/day LOAEL Developmental toxicity
Fertility and Embryonic Development Rat Oral 10 mg/kg/day NOAEL No effects at maximum dose, Not Teratogenic
Fertility and Embryonic Development Rabbit Oral 10 mg/kg/day NOAEL No effects at maximum dose, Not Teratogenic

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Piroxicam
In Vitro Bacterial Mutagenicity (Ames) Salmonella , E. coli Negative
In Vitro Cytogenetics Human Lymphocytes Negative

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Piroxicam
2 Year(s) Rat Oral 1 mg/kg/day NOAEL Not carcinogenic

Carcinogen Status: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

Environmental Overview: The environmental characteristics of this mixture have not been fully evaluated. Releases to the environment should be avoided.
13. DISPOSAL CONSIDERATIONS

Disposal Procedures: Dispose of waste in accordance with all applicable laws and regulations.

14. TRANSPORT INFORMATION

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

EU Symbol: T
EU Indication of danger: Toxic to reproduction: Category 1
Harmful

EU Risk Phrases: R48/22 - Harmful: danger of serious damage to health by prolonged exposure if swallowed.
R61 - May cause harm to the unborn child.

EU Safety Phrases: S22 - Do not breathe dust.
S36 - Wear suitable protective clothing.
S53 - Avoid exposure - obtain special instructions before use.

OSHA Label:
WARNING
May be harmful if swallowed.
May damage the unborn child.
May cause allergic reaction in aspirin-sensitive individuals
Can cause gastrointestinal and kidney effects
May cause blood, liver, and central nervous system effects

Canada - WHMIS: Classifications

WHMIS hazard class:
Class D, Division 2, Subdivision A

Piroxicam
Australia (AICS): Present
Standard for the Uniform Scheduling for Drugs and Poisons: Schedule 4
EU EINECS List: 252-974-3

Propyl gallate
Inventory - United States TSCA - Sect. 8(b): Present
Australia (AICS): Present
MATERIAL SAFETY DATA SHEET

Material Name: Piroxicam Suppositories
Revision date: 04-Jan-2007

16. OTHER INFORMATION

Reasons for Revision:
Updated Section 3 - Hazard Identification. Updated Section 5 - Fire Fighting Measures.
Updated Section 6 - Accidental Release Measures. Updated Section 8 - Exposure Controls /
Personal Protection. Updated Section 15 - Regulatory Information.

Prepared by:
Toxicology and Hazard Communication
Pfizer Global Environment, Health, and Safety

Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without a warranty of any kind, expressed or implied.

End of Safety Data Sheet